VES-MATIC CUBE 80

OPERATING MANUAL

Software release n. 2.24

Automatic professional laboratory device for the determination of the erythrocyte sedimentation rate (ESR)

(patented)

DIESSE

INNOVATIVE CLINICAL DIAGNOSTIC SYSTEMS

MANUFACTURER/AGENT

DIESSE DIAGNOSTICA SENESE S.p.A.

Via delle Rose 10, 53035 Monteriggioni (SI), Italy

Tel. ++39 0577 587111 Fax. ++39 0577 318690

www.diesse.it

LEGAL REPRESENTATIVE

MANAGING DIRECTOR

Dr. Francesco Cocola

REGISTERED AND ADMINISTRATIVE OFFICE

Via S. Vittore 36/1, 20123 MILANO, Italy

Tel. ++39 02 4859121 Fax. ++39 02 48008530

SERVICE ASSISTANCE

CUSTOMER CARE

Via del Pozzo 5, 53035 Monteriggioni (SI), Italy

Tel. ++39 0577 319556 Fax. ++39 0577 319020

e-mail: customercare@diesse.it

DIESSE INC.

1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.

Phone: (305) 827-5761 | 1-877-DIESSE-3 | Fax: (305) 827-5762

e-mail: salesoffice@diesse.us

ASSISTANCE SERVICE

DIESSE INC.

1690 W 38 Place, Unit B1 Hialeah, FL 33012, U.S.A.

Phone: 800 582 1937

TECHNICAL ASSISTANCE

DIESSE INC. CUSTOMER CARE

CUSTOMER CARE

1690 W 38th Place, Unit Bi Hialeah, FL 33012

Tel. 1 (877) 343-7733 Fax. (305) 827-5762

e-mail: customercare@diesse.us

Printed in 2009 (Total pages: 91)

ATTENTION: this manual consists of 91 pages. It is to be used only when complete. If not, DIESSE Diagnostica Senese S.p.A. declines all responsibility. It is possible to request a new copy from Servizio Customer Care - Via del Pozzo 5, 53035 Monteriggioni (SI), Italy. Tel. ++39 0577 319556 Fax. ++39 0577 319020; e-mail: customercare@diesse.it.

Standards applied to the present document
UNI EN 591 II Edition (November 2001)
IEC 61010-1-04
IEC 61010-1-04

SYMBOLS

Key of graphic symbols used on the instrument (European Standard: EN980:2003].

Instrument that fulfils the requirements of the European directive on in vitro diagnostic devices (98/79/EC)

Instrument that complies with CSA standards for the Canadian and US markets

In vitro diagnostic medical device

Manufacturing date:

Serial number

Key of electric and safety symbols used for the instrument.

Caution, electrical shock danger

Attention, read the manual, observe the symbols regarding safety.

WEEE: **Waste from Electrical and Electronic Equipment** - Obligation of separate waste collection according to L.D. 25/07/2005 no. 151 (Italy), enforcement of the 2002/96/EC and 2003/108/EC directives

Key of symbols used in this document

ATTENTION, potential hazard of personal injuries, all conditions indicated in the text must be read and understood before proceeding.

CAUTION, potential danger of damage to the machine, all conditions indicated in the text must be read and understood before proceeding.

N.B. important information.

BIOHAZARD, danger of contamination with possibly infected materials

LIMITATIONS AND WARNINGS

Before installation and use of the instrument, **for proper and safe use**, it is advisable to **read carefully** the warnings and instructions contained in this user manual. It is important that this user manual is stored together with the device for future reference.

In the event of sale or transfer, make sure that this manual accompanies the Ves-Matic Cube 80 to allow new users to be informed about the instrument's functions and the related warnings.

Use of this instrument is recommended by **qualified and skilled personnel only**. The installation must be carried out by an authorised Diesse Diagnostica Senese S.p.A. technician who will create an **Installation Report** supplied separately with the Installation Check Guide.

This **Report** must be sent to the Diesse Diagnostica Senese S.p.A. Technical Service Department in charge to allow the effectiveness of any technical interventions and assistance after installation.

	It is important that this user manual is kept with the device for future reference.
	In the case of sale or transfer, make sure that this manual accompanies the Ves-Matic Cube 80 to allow the new users to be informed about the instrument functionality and its related warnings.
	The Ves-Matic Cube 80 instrument must be used by qualified laboratory personnel previously trained by Diesse Diagnostica Senese S.p.A. or by companies nominated thereby.
	IN CASE OF FIRE OR GENERAL DANGER, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE
	**DISCONNECT** the machine from the power source before any technical intervention or in the case of malfunctioning of the instrument.
	Only use **finger pressure** to key in the commands of the display and/or the keyboard
	**It is PROHIBITED to operate** the machine while any parts are moving (users are only permitted to key in commands on the keyboard).
	ATTENTION: The machine is designed to work with the door closed.

	**Reagents and Consumables** Any materials and/or accessories supplied for the Ves-Matic Cube 80 are specially designed and cannot be replaced with other types of materials or supplies. Using other material types can seriously jeopardise the performance of the instrument. Diesse Diagnostica Senese S.p.A. declines all responsibility for the performance of the product if original reagents and materials are not used.
	Before carrying out any maintenance: -unplug the machine from the power source -use the individual protection devices foreseen by current regulations -do not take remove the covers or bypass the safety devices
	Samples that are not treated correctly may not guarantee a good end result
	Improper use and lack of or incorrect maintenance could seriously jeopardise the analytical process.

The safety and performance requirements of the instrument can no longer be guaranteed when the instrument is powered using a different cable from the one supplied, compatible with the power supply of the country of installation.

BIO-CONTAMINATION HAZARDS

	Potentially infected material is treated. When an analysis system like the Ves-Matic Cube 80 is used, all precautions must be taken regarding biological risks. The samples do not require preparation. The samples must be disposed off in accordance with the laboratory instructions and with local laws. Observe personal and group safety measures planned for the operator and appropriate for the work environment. Comply with the DIRECTIVES on safety matters and with the laws in force.
	In the case of leakage of biological material, during the working cycle, clean external surfaces of the instrument using appropriate laboratory safety devices in order to ensure personnel safety (see paragraph 5.2)
	All supplied materials must be disposed off in accordance with the local laws.

INDEX

1 CHAPTER 1

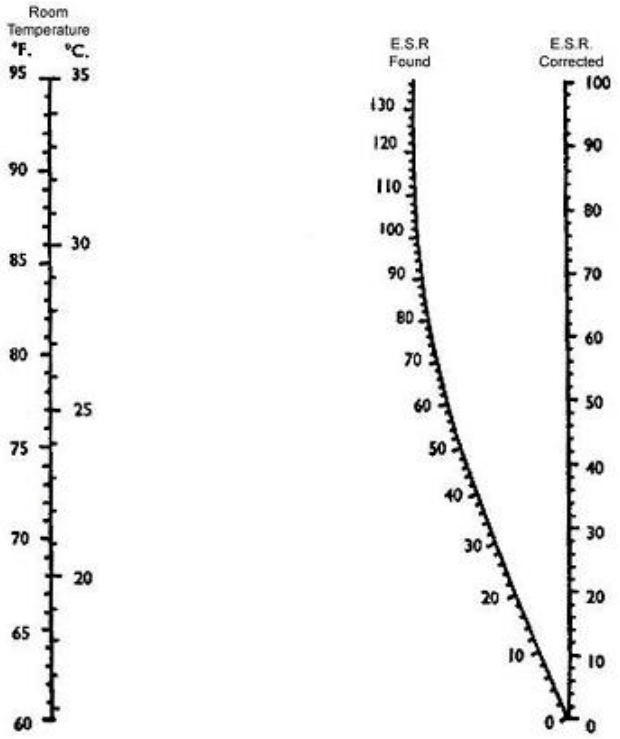
1.1 PRESENTATION OF THE INSTRUMENT

The Ves-Matic Cube 80 is a bench top instrument designed and programmed to determine the Erythrocyte Sedimentation Rate (ESR) with continuous and random loading of samples. It is able to analyse up to a maximum of 90 blood samples every hour.

The instrument carries out the ESR analysis directly from the test tubes being used on the blood cell counter in the laboratory; duplicate samples or extravasation of biological material are therefore unnecessary.

The instrument is managed by an on-board, touch screen PC and its functionality will be described in more detail in the forthcoming paragraphs.

The analysis is carried out completely automatically (mixing and reading) and the results, obtained in only 20 minutes, are comparable to those obtained with the Westergren Reference method in 1 hour (ref. 1-10). The instrument is designed with the temperature correction always activated and relates the results to a temperature of 18°C according to Manley's Nomogram (graph 1.1). However, it is possible to de-select the temperature correction for individual laboratory needs.



Graph 1.1 Manley's Nomogram

Clinical concept of the ESR

The Erythrocyte Sedimentation Rate (ESR) is the measurement of the speed with which the erythrocytes settle. The ESR value measured in a specific moment is influenced by the plasma concentration of some proteins. This concentration is changed in inflammatory situations and also in the presence of certain pathologies, for example some neoplasms. The ESR value is also influenced by some erythrocyte properties and the haematocrit value.
Extremely high ESR values are typical in multiple myeloma, leukaemia, lymphoma, breast and lung carcinomas, rheumatoid arthritis, SLE, pulmonary infarction. It is high in infections of any type, in carcinoma, in the presence of liver metastasis, acute and chronic inflammations.

General functioning of the instrument:

The blood obtained in the CBC (cell blood count) test tube examination, is carefully mixed by the instrument; the samples then remain at rest for a predetermined amount of time, to allow sedimentation to occur.
Through analogue sensors (optic-electronic groups), the instrument automatically determines the sedimentation level of the erythrocytes; subsequently the information is extrapolated and then automatically printed or shown on the display (in the case of a host connection, please read paragraph 7.2)
The analytical results are obtained from the internal processing of the readings; the values obtained are correlated with the Westergren (citrate) reference method. The instrument is designed to express the results of the ESR measurement in Westergren citrate units; nevertheless, depending on laboratory requirements, during installation it is possible to select the expression mode of the results in Westergren EDTA units. To select this mode, please contact a specialised technician authorised by DIESSE Diagnostica Senese S.p.A.

Normal ESR values (Westergren citrate)

Normally ESR values are between 1 and 10 mm/hr for men and between 1 and 15 mm/hr for women; in pathological conditions results can increase to values of up to 100 mm/hr and higher.
Indicative normal range of the Ves-Matic Cube 80 instrument (values expressed in Westergren citrate units)

MEN	up to 10 mm/hr
WOMEN	up to 15 mm/hr

These values must be considered as indicative and vary depending on age and gender.

Normal ESR values (Westergren EDTA)

In general, since the ESR value varies with age and gender, the reference values should respect this characteristic and should be established in relation to gender and age. The reference values should be established by the laboratory and in accordance with the “Guidelines for the determination of the reference values”. Furthermore, there are other clinical variables (for example: the level of haemoglobin, some medicines, the menstrual cycle, pregnancy, smoking) that can influence ESR values and thus reflect also on the physiological reference values. To evaluate the

values in EDTA consult the table present in the reference document: ICSH Recommendations for measurement of erythrocyte sedimentation rate. J. Clin. Pathol. 1993; **46**: 198-203.

1.2 GENERAL DESCRIPTION OF THE INSTRUMENT

Fig. 1.2.1 “front view closed”

Legend fig. 1.2.1 “front view closed”:

① Instrument control unit with display equipped with Touch Screen PC Tablet
② Printer
③ Rack introduction compartment

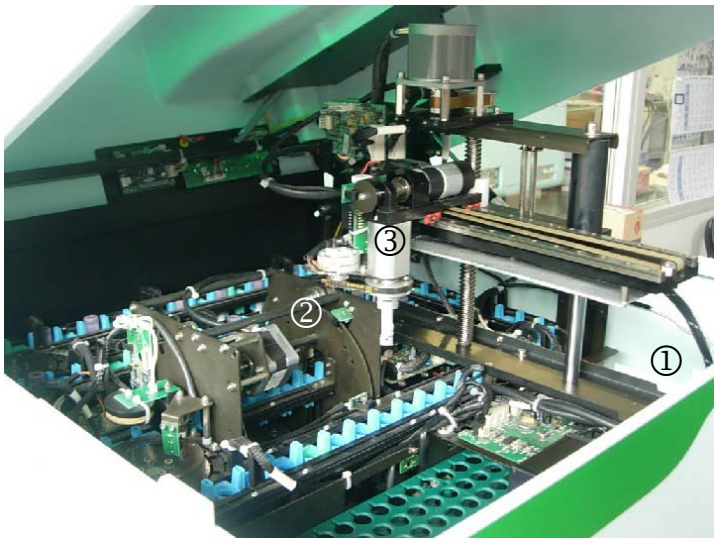


Fig. 1.2.2 “front view open”

Legend fig. 1.2.2 “front view open”

① Sample rack introduction compartment
② mixer
③ Sample tube withdrawal clamp

fig.1.2.3 ‘Rear view’

Legend fig.1.2.3 Rear View

① External connections panel

② Power supply box

fig.1.2.4 ‘Detail of connection panel’

Legend fig.1.2.4 ‘ Detail of the connection panel

① RS232 connector (for connection to the Host Computer)

② EXTERNAL BARCODE reader connector

③ USB_HOST connector

fig.1.2.5 ‘Detail of power supply box’

Legend fig.1.2.5 ‘Detail power supply box’

① Switch “ I “ [ON] / “O” [OFF]

② Filtered outlet with fuse holder lodging

1.2.1 Compatibility with test tubes used for the CBC test

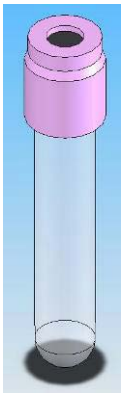
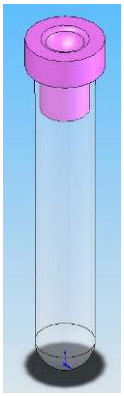
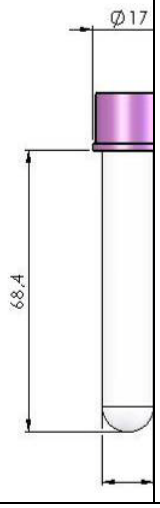
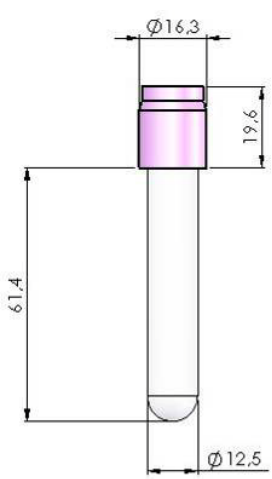
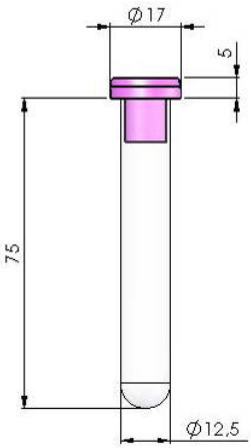
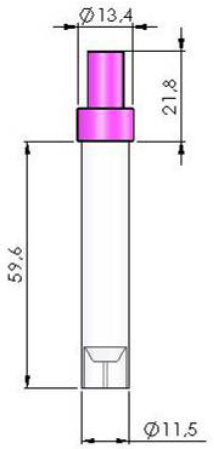
	VACUETTE (GREINER BIO-ONE)	VACUTAINER (BD)	'RUBBER' [RUBBER CAP, BD TERUMO]	'SARSTEDT'
Model				
Dimensions (mm)				

fig. 1.2.2.1

The Ves-Matic Cube 80 is configured to use the same test tubes coming from the blood cell counter in the laboratory.

The compatible test tubes are those described in fig. 1.2.2.1

The test tube models described in figure1.2.2.1 are substantially different in height, diameter, shape and dimensions of the cap, but it is nevertheless possible to use different test tubes at the same time.

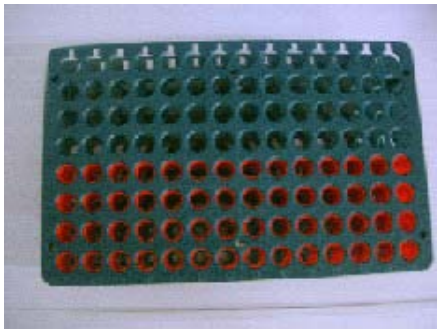
If the type of test tube being used is not displayed in the above examples, it is possible to request that the instrument be programmed to make it compatible with the desired test tube type. This modification can only be carried out by a specialised technician authorised by DIESSE Diagnostica Senese S.p.A.

<{100{>**fi**

1.3 MATERIALS SUPPLIED WITH THE INSTRUMENT

The Ves-Matic Cube 80 is supplied with the following materials:

- 1 Operating Manual, in ENGLISH (hard copy) [Ref: R30600540]
- 2 Sample holder racks [Ref: R30003650)
- 2 Input extension racks [Ref: R10338870]
- 2 Lifting handles [Ref: R10340531]
- 2 V.2 Micro switch keys [Ref: R10345960]
- 1 Roll of H.mm L=57 D=50 thermal paper [Ref: R12300000]
- 2 5x20mm UL 5A delayed fuses [Ref: R20400070]
- 1 3x0.75 L =2m SCHUKO 90°-C13 Power cable [Ref: R21890040]
- 1 SVT PLUG USA/OUTLET VDE 2MT UL Power cable [Ref: R21890370]
- 1 Z-3080+ Barcode reader Cable CAB50607-R9 [Ref: R20550510]
- 1 Packing-list
- 1 Installation guide
- 1 Warranty Card
- 1 Final Inspection report



Sample holder Rack

Micro switch keys V.2

Barcode reader Z-3080+Cable CAB50607

5x20 mm UL 5A delayed fuses

3x0.75 L=2m SCHUKO 90°- C13 Power cable

Rack Input Extension

Roll of thermal paper H.mm L=57 D=50

SVT PLUG USA/SOCKET VDE 2MT UL Power

Consumables that can be purchased for using the instrument

▪ Check Device Transponder RF 1K for Ves-Matic Cube (1000 tests)	[Ref: 10292]
▪ Check Device Transponder RF 5K for Ves-Matic Cube (5000 tests)	[Ref: 10291]
▪ Check Device Transponder RF 10K for Ves-Matic Cube (10000 hits)	[Ref: 10290]
▪ ESR Control 9 ml (2 Normal Bottles + 2 Abnormal Bottles)	[Ref: 10430
▪ ESR Control 9 ml (1 Normal Bottle + 1 Abnormal Bottle)	[Ref: 10434]
▪ Thermal paper for printer (1 pack)	[Ref: 10403]

The safety and performance requirements of the instrument can no longer be guaranteed when the instrument is powered using a different cable from the one supplied, compatible with the power supply of the country of installation.

The safety and performance requirements of the instrument are not guaranteed whenever the instrument is used with different materials from the ones supplied and shown below:

External barcode reader, moulded sample holder rack, delayed 5A fuses (5x20 mm) UL, internal barcode reader programming guide.

1.4 TECHNICAL SPECIFICATIONS

Current	Europe: 230Vac@50Hz; USA/Canada: 110-120Vac@60Hz	
Absorbed electric power	265VA	
Fuses	2 x 5.0 AT (Delayed) (5 x 20 mm) UL	
Dimensions	650 x 580 x 690 mm (l x h x d)	
Weight	45 Kg	
Room temperature	In use	from +15 to +35°C
	Warehouse	from + 5°C to + 45°C
Allowable relative humidity	from 20% to 80% without condensation	
Central unit	Freescale i.MX31 ARM11 Microprocessor; Flash 128MB NAND; 128 MB DDR RAM	
Display	TFT 800x 600 colour with Touch Screen	
Control unit peripherals	Microprocessor card on owner bus	
Internal analytic section	89 position chain for the appropriate test tube	
Step progress chain	19 seconds in the normal functioning	
Analysed samples collection section	8x14 position sample holder rack (4x14 samples to be analysed and 4x14 analysed)	
Optic groups	Two couples of optic-electronic elements (Led & analogical sensor)	
Printer	Alphanumeric with thermal paper 58 mm wide, 36 characters per line, speed 20 mm/sec.	
Interface	2 x RS232C, 2 USB Host, 1 USB Client, 1 Slot Compact Flash	
Protection category	CLASS I	
Safety standards	CEI EN 61010-1 (Ed.2001-11); CAN/CSA-C22.2 Nr.61010-1-04 (Ed.2004-07); UL61010-1 (Ed.2004-07)	
EMC	CEI EN 61326 (Ed.2004-08)	
Installation category	II	

1.5 TECHNICAL DESCRIPTION OF THE INSTRUMENT

The "Window group" consists of :

- 'PC TABLET'- CENTRAL UNIT

  Herein resides the application software that controls, manages and receives data, via serial connection from the single peripheral microprocessor cards where the EEPROM resides and all parameters of the instrument are memorised.

  It is fitted with:

- DISPLAY

  This allows the display of and interaction with (by means of a touch screen) all the software functions.

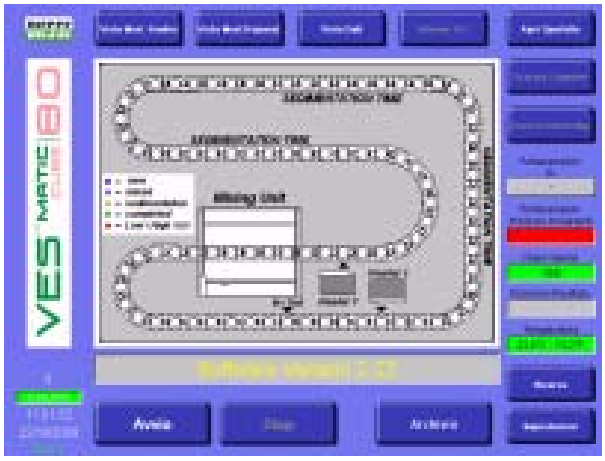


fig. 2.1 a

fig. 2.1 b

- KEYBOARD

  The keyboard functions are carried out both using the touch screen system (fig. 2.1.) that allows interaction with all the control software functions,
  and with the 7 keys (fig. 2.2) located on the PC Tablet frame:

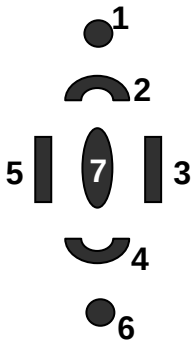


fig. 2.2

Description of the key controls:

1 and **6** inactive
2 the pointer moves upwards
3 the pointer moves towards the right
4 the pointer moves downwards
5 the pointer moves towards the left
7 "invio" ("enter")

- ACOUSTIC SIGNAL SYSTEM

  This functions as an alert for the operator during specific phases of the work cycle: Whenever the instrument is switched on, it emits a special signal; each time a button on the keyboard is pressed it emits a characteristic “beep”, and additionally, to signal a problem it emits a specific alarm sound.

- PRINTER

  This prints the information regarding the processed test tubes (sample code, ESR result) contained in the sample holder rack and all useful information regarding the working cycle (date, hour, temperature). For a detailed description see paragraph 3.4.

The “Preparer Module” consists of:

- SAMPLE PRESENCE DETECTION UNIT

  The unit comprises a group of sensors that allow the machine to understand whether and where the samples are inside the rack

- BARCODE READING UNIT

  This unit carries out the barcode reading of each sample so that the instrument can execute a Host Query to differentiate the test tubes that require an ESR and thus must be inserted in the test tube holder chain.

  The samples for which an ESR is not required can instead be placed in the rack

- CLAMP UNIT

  This unit is the connection between the preparatory module and the analysis module. It comprises pincers activated by four motors that allow the transfers:

  - The samples still to be analysed are then taken from the rack and brought before the barcode reader
  - to read the barcode and are then inserted in the test tube holder chain (or placed in the rack if the specific sample does not need analysing).
  - The analysed samples are then taken from the chain, thanks to a piston that pushes the test tube outside the link to allow the pincers to grip it.

- RACK PULLING UNIT

  With the help of belts positioned on the base, this unit moves the sample holder rack along the module to allow the test tube transfer unit to load and unload the samples from all the rack positions.

  The sample holder racks ejected from the instrument must be refrigerated.

  To locate a specific sample the Ves-Matic Cube 80 provides the sample code and its location coordinates in the sample holder rack, which itself is identified by a specific code.

The "Analysis module" consists of:

- POWER SUPPLY UNIT
  Mainly comprising 3 switching power suppliers; it supplies the electricity to the various modules following a criterion for the allocation of load.

- TEST TUBE HOLDER CHAIN
  The test tube holder chain consists of 89 links in which the test tubes are inserted; with the help of two traction wheels, the chain rotates clockwise inside the analysis module, transferring the test tubes to the mixing unit and subsequently to the reading units.
  The speed of the chain movement is controlled to allow the samples to settle for a period of 20 minutes before the final reading is carried out.

- MIXING UNIT
  This is the unit in charge of the inclination and 120° rotation of the test tube holder chain for 5 test tubes, to guarantee the homogenous mixing of the red blood cells.

- READING UNITS 1 & 2
  In each unit, a motor lifts the reading unit that, with the help of an optical sensor, verifies the suitability of the sample contained in the test tube and detects the level of sedimentation.

- TEMPERATURE SENSOR
  This measures the temperature inside the instrument and is positioned in the analysis module. The value of the temperature is visible in the "temperature window" on the display.

- EJECTOR UNIT
  This comprises a piston that pushes the test tube outside the chain in order to be picked up by the pincers that will place it in the sample holder rack.

1.6 INFORMATION REGARDING DISPOSAL

The Ves-Matic Cube 80 instrument relies on the use of an electrical power source and therefore, in compliance with European Directive 2002/96/EC of 27 January 2003 and later amendments by the European parliament, it is classified as Electrical-Electronic Equipment. [L.D.25/07/2005 no. 151 (Italy)]

Therefore:
Disposal of the device in the normal solid urban waste is **strictly prohibited** by law. Doing so could incur legal penalties against the violator.
At the end of the product lifecycle it is **obligatory** to carry out **separate waste collection** of the product: contact the manufacturer or the distributor for the disposal or the redelivery of the instrument

For the USA market

Therefore:
At the end of the product lifecycle it is **obligatory** to carry out **separate waste collection** of the product: contact the manufacturer or the distributor for the disposal or the redelivery of the instrument

2 CHAPTER 2

2.1 PREPARATION AND CHECKS BEFORE INSTALLATION
2.2 PLACEMENT
2.3 LIMITATIONS AND WARNINGS

The INSTALLATION must be carried out by a Technical Installer authorised by Diesse Diagnostica Senese SpA with a subsequent Installation Report. Refer to the Installation Check guide.

DISCONNECTION and **SHIPMENT** of the instrument must be performed by a Technician authorised by DIESSE Diagnostica Senese S.p.A.

2.1 PREPARATION AND CHECKS BEFORE INSTALLATION

The following conditions must be ensured for the safety of the instrument and the operator:

The power source (installation category II) must be compatible with the electrical requirements, specifications and current indicated on the electric power plate supplied on the rear of the instrument; it is advisable that the efficiency of the electrical system is periodically verified. The network and relative outlets must be fitted with an efficient earthing connection following the laws in force on the matter of electrical systems.

Before connecting with external instruments (host, PC external Barcode Reader), always remember to do this while the instrument is switched off; it is necessary to verify compatibility (see the relative user manual) with the specifics indicated in chapter 7 and verify that the earth connection between them is uninterrupted. Connection with an external PC is possible with specific software (Microsoft ActiveSync®)

The operator must be trained to ensure awareness of the procedures, restrictions and warnings indicated in this manual in addition to the required laboratory safety procedures.

Items for the security and safety of the operator (gloves, container for the disposal of the consumables used, cleaning and disinfectant solutions for the cleaning and the disinfection of the instrument, see paragraph 5.2) should always be available.

The location of the instrument should follow the guidelines indicated in paragraph 2.2.

IT IS TOTALLY PROHIBITED to remove or modify the safety and protection devices of the instrument.

2.2 PLACEMENT

The environment intended for this instrument is the laboratory.
For normal safety reasons and given the type of analysis carried out, the instrument must be placed away from sources of heat, in areas not accessible to liquids, in environments free from dust and on perfectly flat work benches that are not subject to shocks or vibrations. The Ves-Matic Cube 80 has been manufactured to conform to the electromagnetic emissions directives, however it is nevertheless advised that, whenever possible, the Ves-Matic Cube 80 is placed far from possible generators of electromagnetic waves (for example fridges, laboratory centrifuges) and from instrumentation without CE labelling as they could occasionally interfere with the functioning of the instrument.
It is advisable that a bench that can support the weight of the instrument is used. The bench top should not exceed 90 cm in height, so as to ensure an ergonomically correct position for the operator during the input of the commands on the PC Tablet and the loading and unloading of the sample holder racks in the preparer module.

fig. 2.2.1 frontal view with the extensions for rack input

The bench top where the instrument will be placed, should allow enough space, about 40 cm, on each side of the instrument for the operator to easily load and unload the sample holder rack in the sample module (fig. 2.2.1, fig. 2.2.2 and fig. 2.2.3)
Furthermore, to be able to reach the connectors on the rear of the instrument and, most of all, to be able to access the on/off switch and the power cable quickly in the case of emergency, it is necessary to maintain a safe distance from the wall of at least 20 cm from the rear of the instrument.
It is totally prohibited to place any material on the instrument for the same reason.

fig. 2.2.2. <u>left side</u> of the Ves-Matic Cube 80 (sample holder rack exiting)

fig. 2.2.3. <u>right side</u> of the Ves-Matic Cube 80 (sample holder rack entering)

Choose a position close to an undisturbed electric socket free from electrical fluctuations.

<u>Never move the instrument after it is properly installed.</u> Should movement or relocation of the instrument be necessary, a re-verification of the conditions listed in this paragraph would be required before using the instrument again. Whenever the instrument will not be used for an extended period of time it is suggested that it is disconnected from the power source and protected from dust.

To move the instrument, always apply the supplied handles to the instrument to move the instrument, as shown in sequence (fig. 2.2.4, a,b,c)

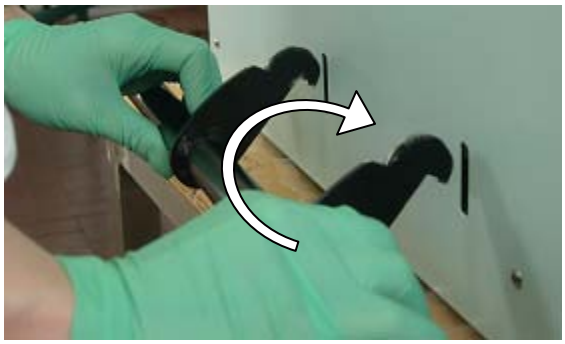


fig.2.2.4 a

fig.2.2.4 b

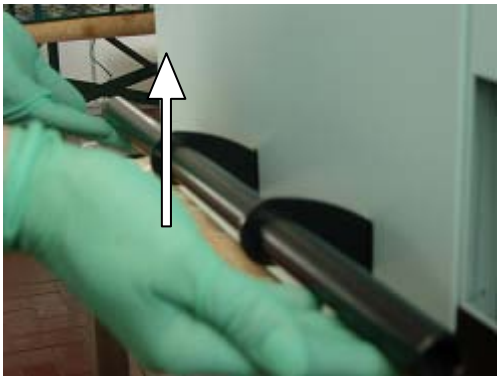
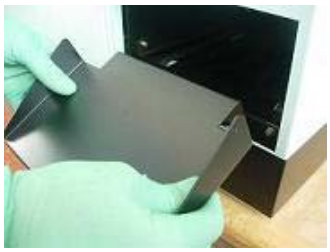


fig.2.3.4 c

<u>During the movement of the analyser avoid blows and excessive inclination that could cause damage.</u>

1. Assure that the **power switch is in the OFF "0"** position before continuing.
2. Plug connections with external instruments (see paragraph 2.1).
3. Install the rack insert extension as shown in the photographic sequence.


4. Before connecting the instrument to the power supply, make sure that the network voltage is compatible with the specifications on the registration label on the back of the instrument.
5. Connect the socket on the power cable (use the cable that is supplied with the instrument) to the plug on the right side of the general power switch on the instrument itself (as shown in fig. 2.2.5 and 2.1.5). Connect the plug of the power cable to the power source.

fig. 2.2.5

6. Turn the instrument on by the general switch, on the back of the instrument, to position **"I"** (fig. 2.2.5).
7. To execute a test cycle and subsequently an analytical cycle, check chapter 4 of this manual. Also after a long period of not using the instrument it is advisable to contact technical assistance to verify the good functioning.
8. Test cycle: Insert a rack with at least 5 labelled test tubes and start the analytical procedure. Check that: the instrument executes the initial "reset" in a correct manner, that the procedure finishes correctly without interruptions, that the barcodes attached to the processed test tubes have been acquired by the instrument correctly (the print concerning the conducted analytical cycle facilitates this verification operation).

Remember that the test tubes to be analysed must be inserted into the red part of the rack as the green part is used by the instrument to unload the samples already analysed.

2.3 LIMITATIONS AND WARNINGS

IN CASE OF FIRE OR GENERAL DANGER, TURN OFF THE INSTRUMENT AND UNPLUG THE POWER CABLE

DISCONNECT the machine from the power source, before any technical intervention or in the case of malfunctioning of the instrument.

It is forbidden to WORK on the machine while parts are moving (it is only allowed to key in commands on the touch screen and/or introduce and remove racks).

Limitations regarding the Check Device (consumable buyable for the use of the instrument): the instrument is provided with special *"Ves Check Device Transponder RF" (see paragraph 1.3)* destined to refill the "test counter" ("Check Device") of the instrument (see paragraph 3.3).

Using other material types can seriously jeopardise the performance of the instrument.
DIESSE SpA declines all responsibility on the performance of the instrument if the materials used are different from those indicated in this manual.

All ***Check Device test tubes*** supplied can be used only once and cannot be used again.
All **Check Device test tubes** are electronic devices and when exhausted must be disposed of according to the laws in force.

Potentially infected material is treated

When the Ves-Matic Cube 80 is used all precautions regarding the biological risk must be assumed.
The consumables must be disposed of according to the laboratory instructions and the laws in force.
Observe personal and group safety measures foreseen for the operator and appropriate for the work environment. Comply with the instructions in security matter and with the laws in force.

3 CHAPTER 3

3.1 SWITCHING ON THE INSTRUMENT

Switching on

After verification of the installation of the instrument as described in chapter 2, make sure the window is closed and move the power switch, situated on the left of the power cable on the back of the instrument, to the on position “I” (fig. 2.5)

Start up of system

Once switched on, push the “Start” button; the instrument executes an initial Check (“Reset”). This operation is essential and allows for verification of the proper functioning of all internal units and check that the moving parts are in the correct positions.

During the initial check when the instrument is switched on, the Software Version installed and subsequently the indications “RESET IN PROGRESS” are shown on the display.

3.2 DESCRIPTION OF THE SOFTWARE

3.2.1 Main menu

From the Main Menu (fig. 3.2.a), using the function buttons, it is possible to:

- start the analysis with the Ves-Matic Cube 80
- Access the service menu
- Modify the display mode (for example: View Analysis View analysis, Mod. Preparatory mode, Data View)
- Unload samples that remain in the analytical chain of the Analyses Module
- Unload the sample holder rack.
- Access the archives of the instrument
- Open the door

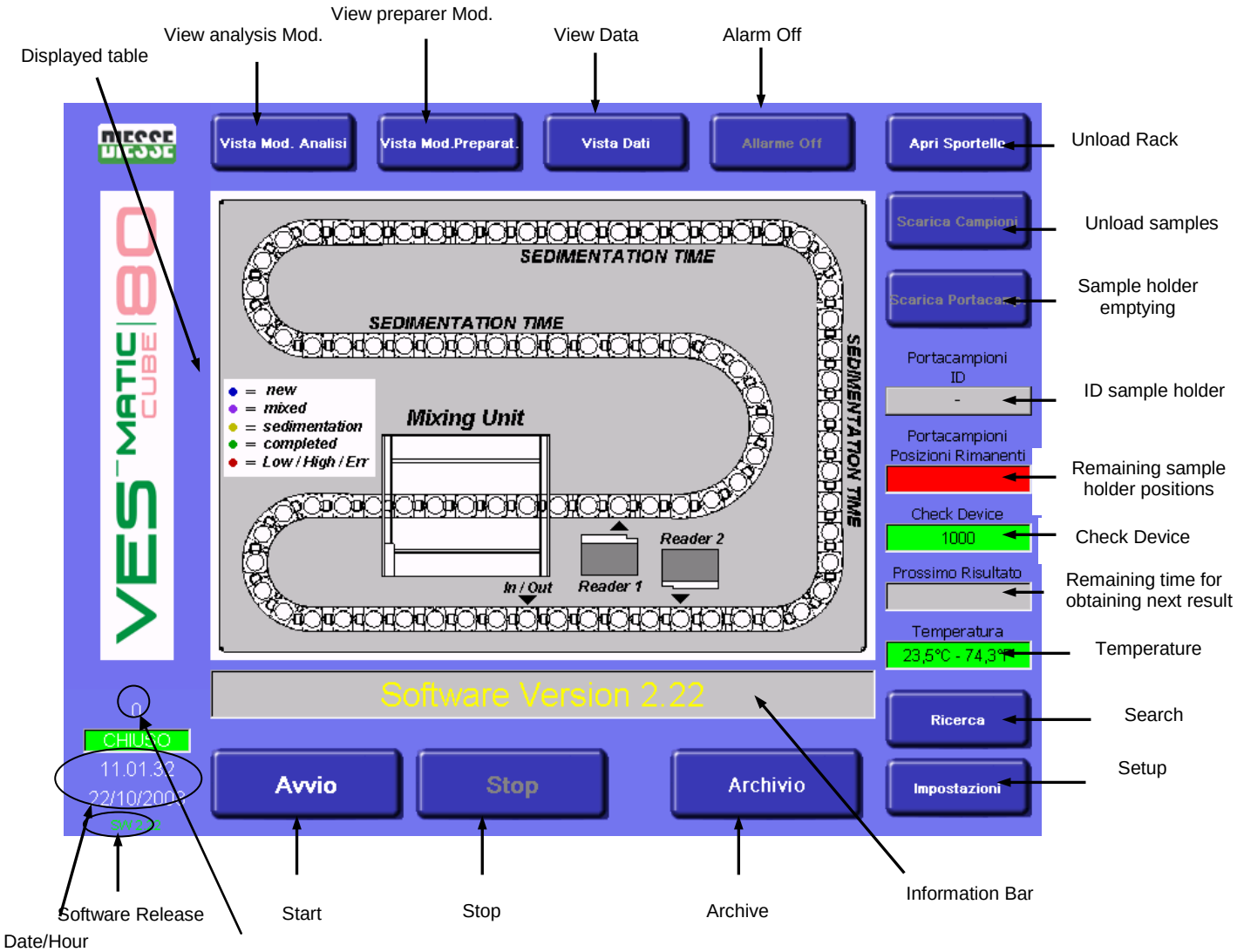


fig.3.2.a

Description of the commands and information common to the 3 modalities

Start: starts the analysis cycle

The Start-up command allows the initialisation of the instrument for the analytical procedures.

Once Start is selected it executes a Reset of the instrument after which it will be possible to insert the samples and proceed with the analysis cycle.

Stop: This interrupts the activity of the instrument. The Stop command interrupts the analytical procedures of the instrument and allows the saving of all analysed sample data. At the end of a normal daily routine and **before** turning off the instrument, it is recommended that users press the Stop button in order to allow the removal of any samples still present in the classifier module and to memorise the analysis in the archive (see paragraph 3.2.2). If the Stop button is pressed during the analytical cycle, a request of confirmation of the stop will automatically appear on the screen with the following message: “STOP Analysis : are you sure? NO YES (fig. 3.2.b). This avoids unwanted interruptions of the analytical cycle.

At the end of a work cycle, remember to press the stop button before turning off the instrument, otherwise the data regarding the last analysis cycle will not be saved inside the archives.

fig.3.2.b

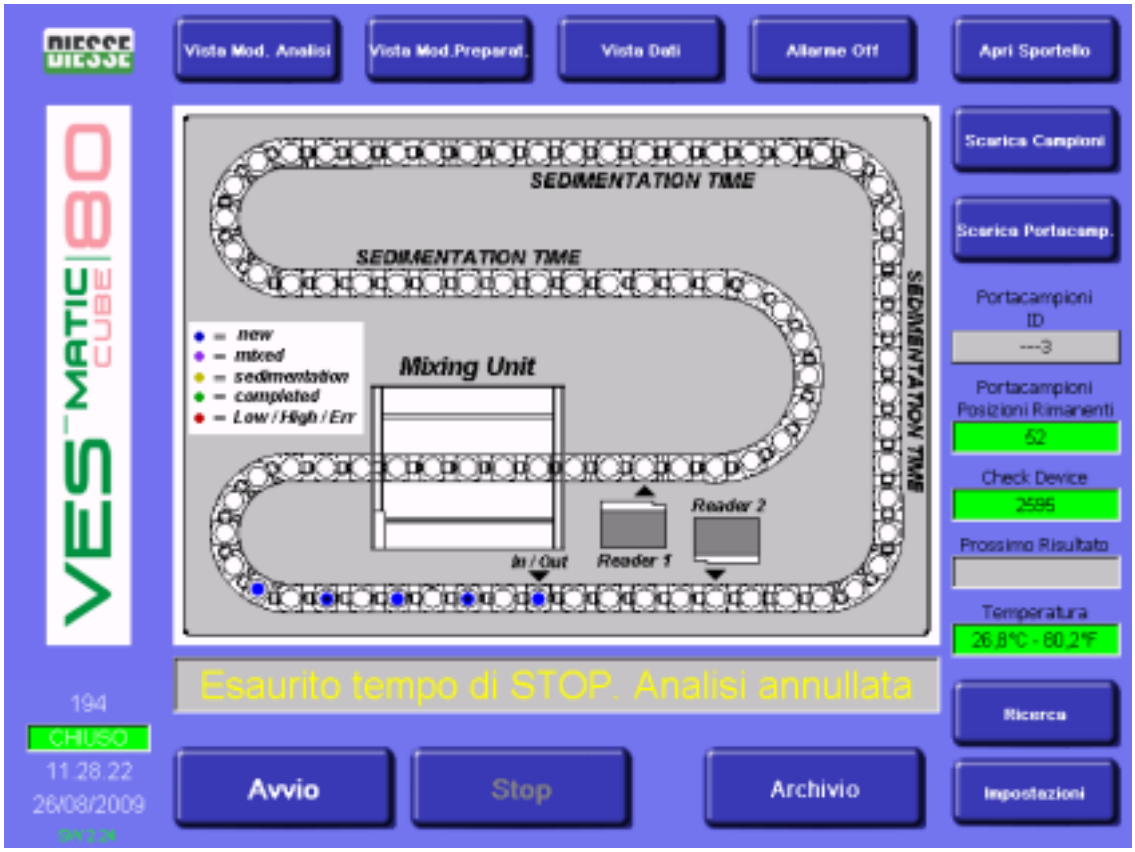


fig.3.2.c

Confirmation of the "YES" button automatically activates a stopwatch of the stop time (decreasing second counter, with the duration of 90 seconds). This maximum interruption time allows the operator to intervene rapidly without changing the sedimentation. The time passed in "STOP" appears in the "Next result" window which will be renamed "STOP Time". At the end of the intervention, that must take less than 90 seconds, it is enough to push the "START" button and the instrument will resume its analytical activity.

If the analyses cycle is re-started within 90 seconds, the instrument will resume the analyses of the samples present in the analytical chain and will complete the reading of the relative ESR; the data corresponding to the test tubes present in the analytical chain during the "Stop time" are not lost and the link of the barcode of each sample with the relative position in the analytical chain is maintained to guarantee a correct correspondence between the data of the sample (especially the link ID (result).

If the analysis isn't restarted within 90 seconds, the analytical run will be cancelled and, after the pushing of the "START" button, the samples present in the chain are not ejected, but sent to a new analytical cycle (shaking, first reading, sedimentation, second reading, and ejection) without a decrease of the check device. In the information bar the message "Expired STOP time: Analysis aborted" will appear, to disappear at the next "Reset" , after pushing the "Start" button (fig. 3.2.c).

Archive: allows access to the database of the instrument

Set-up: allows access to the configuration menu of the instrument (see paragraph "Setup Menu")

Search: allows the search for a sample within the instrument

View Analysis Module: allows the graphical display of the processes inside the Ves-Matic Cube 80 regarding the analysis module

View Preparer Module: Allows the graphical display of the loading/unloading module processes in the rack (preparer module).

View data: allows the display of the data of the samples present in the cycle of analysis

Alarm OFF: deactivates the sound alarms of the instrument

ID Sample holder: indicates the identification number (bar code) of the used sample holder rack

Remaining sample holder positions: indicates how many positions in the sample holder rack are still available

Check Device: indicates the number of tests still executable on the instrument. The green colour of the window indicates that more than 1000 tests are available, orange indicates availability of between 500 and 1000 executable tests, yellow indicates that from 0 to 500 tests remain available, while red indicates that the number of available tests is exhausted. This leads to the automatic block of the transfer of the samples from the preparer module to the analysis module. The samples already in the analysis module are nevertheless read and the relative ESR results are displayed. With the test counter at "0" the instrument is blocked, to execute other tests it will be necessary to recharge the analyser with a Check Device (see paragraph 3.3)

Next Result: indicates the waiting time for the next analytical result

Temperature: indicates the temperature on the inside of the instrument in °C and in °F.

Information bar: shows important information such as the error code (see the table in paragraph 6.1 "Trouble shooting")

Counter of the total number of samples transferred from preparer module to analyses module indicates the total number of samples transferred from the preparer module to the analyses module. To display the total number of tests conducted by the instrument during its 'life' span it is necessary to contact a technician authorised by DIESSE Diagnostica Senese S.p.A

Window OPEN/CLOSED: (OPEN with red background, CLOSED with green background) indicates the status of the sensor present in the lid.

Date/Time: indicates date and time

SW X.XX: indicates the Software version installed on the instrument.

In addition to the commands and information described in the previous paragraph, it is also possible to see an online animation, on the display screen, of the status of the test tubes in terms of position, reported to the various components of the instrument; this information can also be obtained by visual observation of the various colours of the individual samples, as explained in the following image.

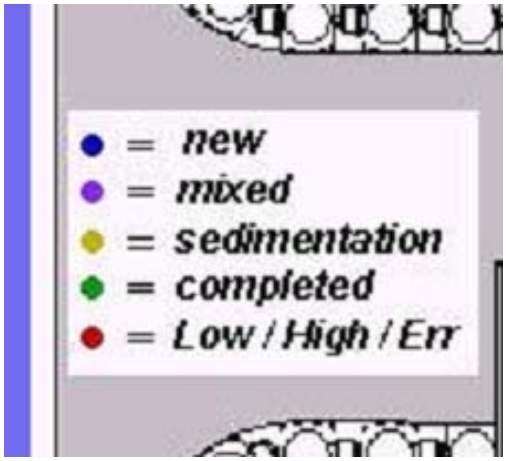


fig.3.2.d (tabella a video)

- = new (new sample to analysed)
- = mixed (sample being mixed)
- = sedimentation (sample in sedimentation)
- = completed (sample analysed)
- = Low/High/Error (sample for which a problem was encountered: blood level to low, to high or an error, for further explanations see paragraph 3.4)

Open the door: This allows the upper door to be opened to check for any irregularities or problems. This button is only open when the cycle has not been started, otherwise the button will be disabled.

Unload samples: Once a cycle has ended (pressing stop), this key allows a scan to be made of the analytical chain and the unloading of test tubes to be detected. If the instrument is turned off and on, this button will be deactivated: to activate it, it will be necessary to press the start button and the stop button at the end of reset.

Unload sample holder: ejects the sample holder rack.

Unload samples procedure

The "Unload samples" procedure recovers automatically all test tubes present in the analytical zone of the instrument, for example recovering an urgent sample or in the case of a forced interruption of the analytical cycle.

SEQUENCE OF OPERATIONS IN CASE OF FORCED INTERRUPTION OF ANALYTICAL CYCLE

1. **Press the START button**
2. **At the end of the reset insert a sample holder rack in the dedicated zone (fig.2.4.3)**
3. **Press the STOP button**
4. **Press the UNLOAD SAMPLES button and wait for the end of the procedure.**

IN CASE OF AN UNLOAD OF SAMPLES WITHOUT BLACKOUT, FOLLOW THE PROCEDURE FROM 3. (if necessary insert a sample holder rack)

Sample holder emptying procedure

The sample holder emptying procedure allows the automatic recovery of all test tubes present in the rearrangement zone of the instrument (sample holder rack); for example to recover an urgent sample or in the case of an instrument block due to a forced interruption of the analytical cycle.

SEQUENCE OF THE OPERATIONS

1. **Press the STOP button**
2. **Press the "UNLOAD SAMPLE HOLDER" button and wait for the end of the procedure.**

Description of the commands and information in the View Preparer module mode

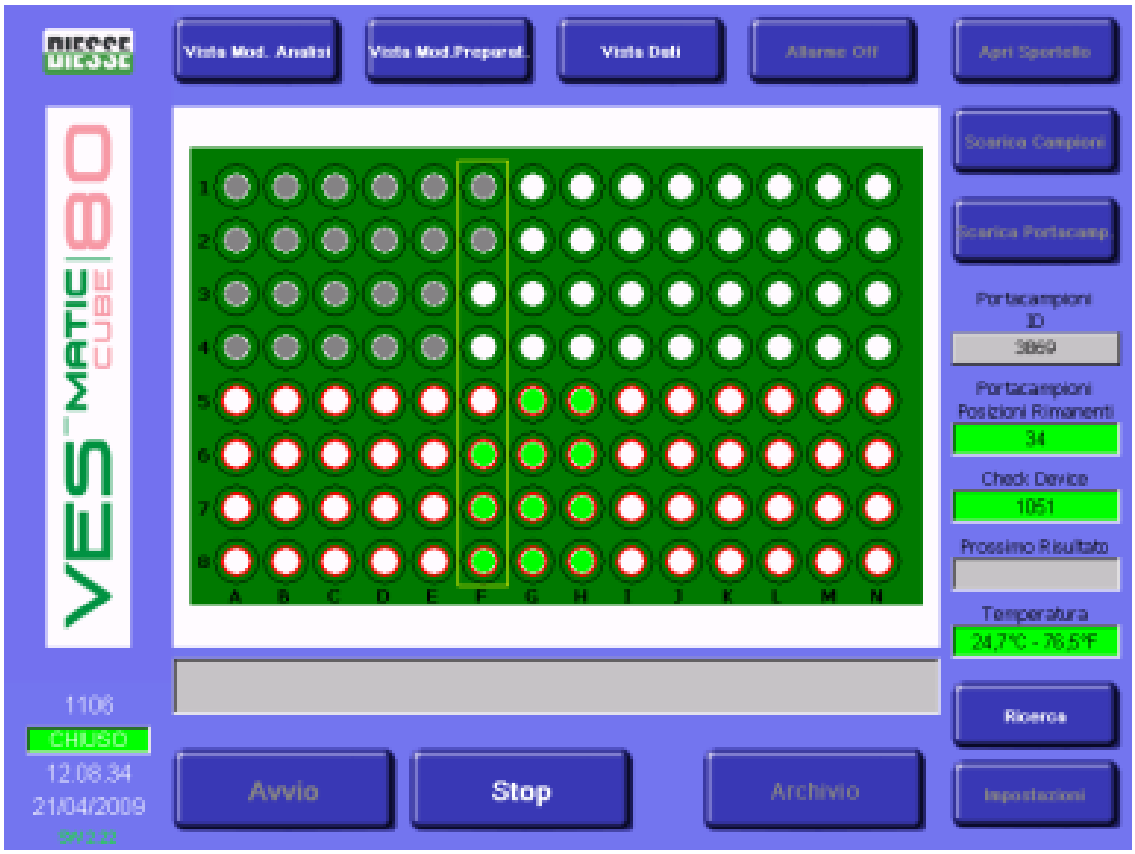


fig.3.2.e

Besides the buttons described in the previous paragraph, there is also an online animation of the status load and unload racks module (fig. 3.2.e)

Colour code of racks in View Preparer module mode.

- = sample tube waiting to be processed
- = empty position or not yet verified by the sensor
- = analysed sample

Description of the commands and information in View Data mode

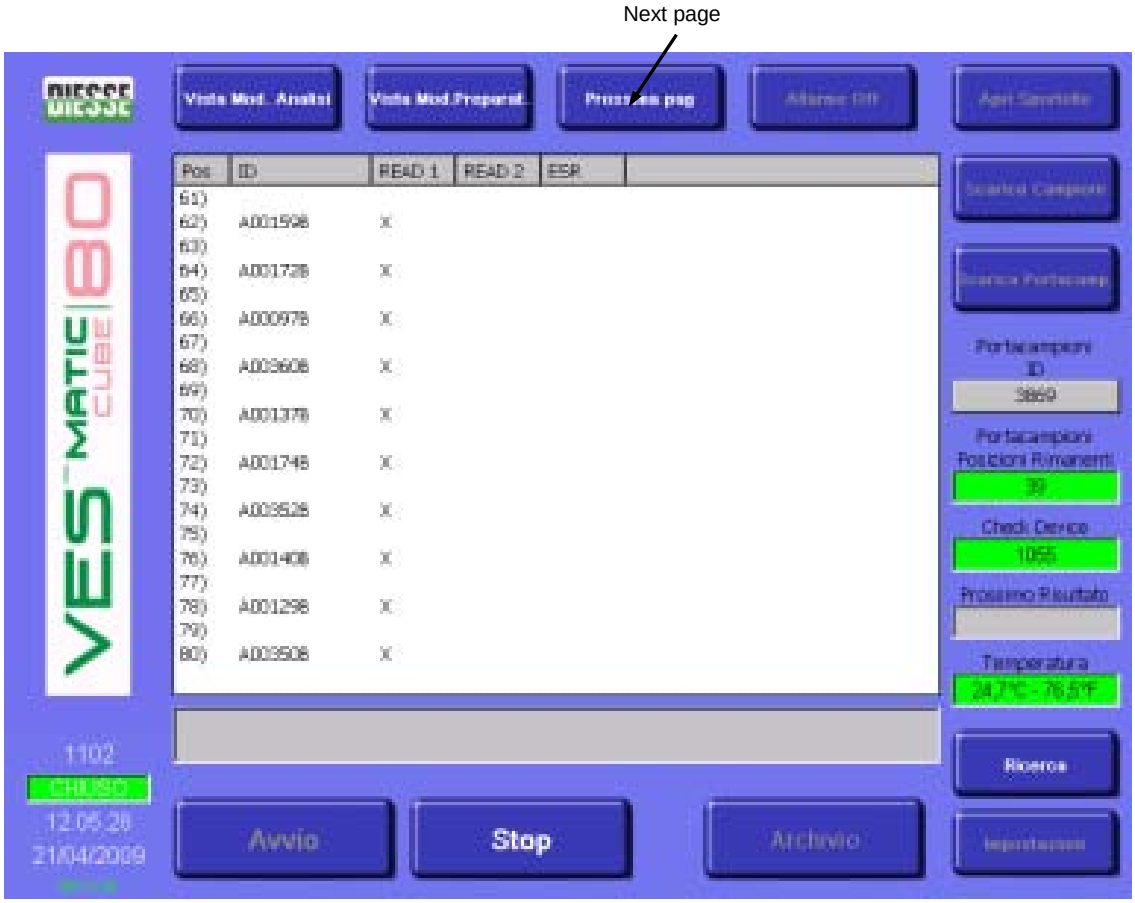


fig. 3.2.f

Next page: allows the display of the next pages

Besides the buttons described in the previous paragraph, it is possible to have information about the samples being analysed. This window displays (fig 3.2.f):

POS: position of the sample in the chain

ID: Identification code of the sample

READ1: Reading no. 1 corresponding to the level of the entire column of blood after mixing. This data can only be seen after typing the specific access code. (Access to this function is only allowed to personnel authorised by DIESSE Diagnostica Senese S.p.A.).

READ2: Reading no. 2 corresponding to the level of the erythrocyte column after mixing. This data can only be seen after typing the specific access code. (Access to this function is only allowed to personnel authorised by DIESSE Diagnostica Senese S.p.A.).

ESR: ESR result

Search function

fig. 3.2.g

The search button allows the detection of a sample on the inside of the Ves-Matic Cube 80 and the possible recovery of it by insertion of its bar code number (fig. 3.2.g) using the keyboard and pressing the OK button.

The **OK** button is replaced by the buttons "**YES**" and "**NO**" to provide the ability to respond to the proposed option (regarding the removal of the sample).

Removal of the sample

Pressing the "**YES**" button will start the recover sample procedure.

ATTENTION

The sample recovery procedure will interrupt the analysis cycle.

3.2.2 Archive menu

Choosing the **ARCHIVE** command in the main menu, the functions of the ARCHIVE Menu are accessed.

Historical DB: allows access to the historical archive of the samples present in the database.

Pending DB: allows access to the archive of the pending samples present in the database. The pending samples are those that are not yet sent by the Host nor saved in the historical archive.

Quality Check DB: allows access to the historical archive of the Quality Control samples present in the database.

Rear: returns to the Main Menu.

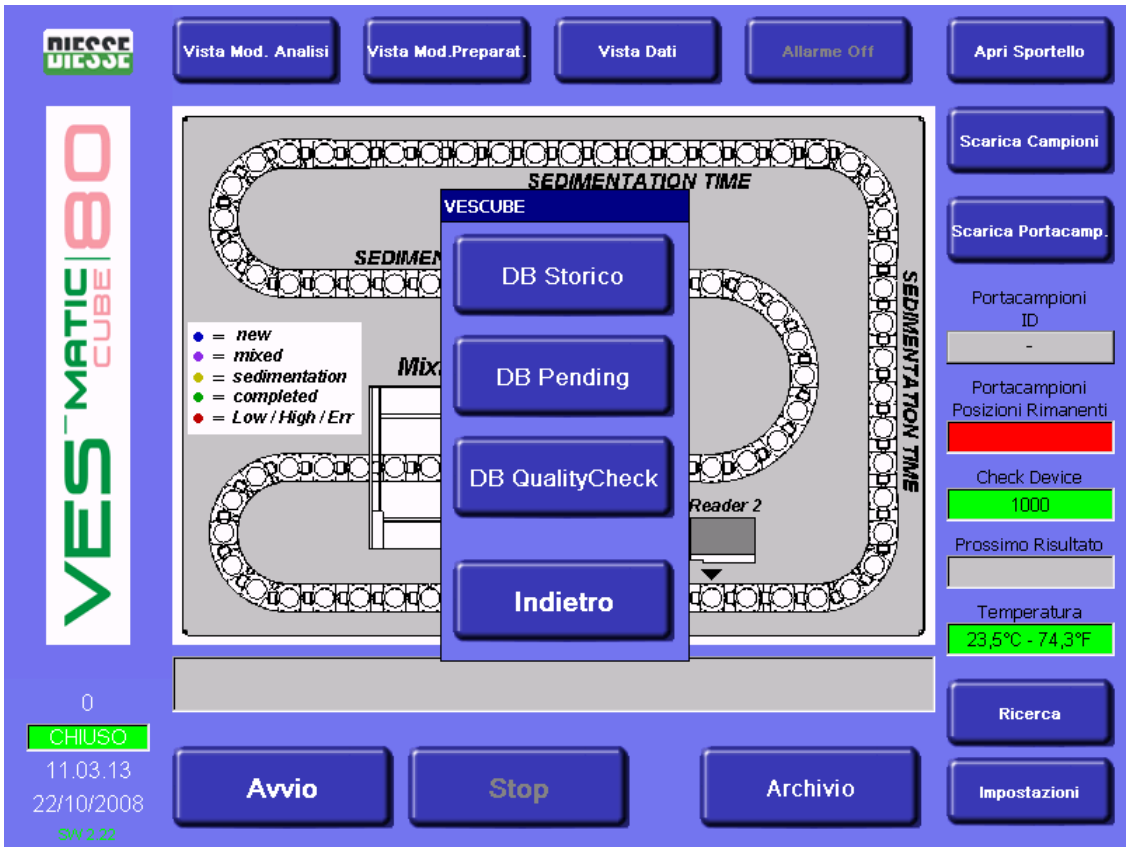


fig. 3.2.h

DATABASE (ARCHIVE)

There are 3 archives (fig. 3.2.h):

The **historical database** (fig.3.2.i) stores up to a maximum of 10,000 samples managed in a scrolling mode. Only those samples for which the host computer, or the operator, has authorised the analysis will be saved in this archive*. It will be possible to see, print and send the results to the host only for these. The check device counter will be reduced only for these results. The samples sent to the host will be highlighted in the display page of this database with an asterisk.

The information (code and position inside the sample holder) about samples on which ESR tests will not be carried out, which for these samples will be O, will be printed, saved in the historical database and sent to the host; this intervention on configuration software is only allowed by technicians authorised by DIESSE Diagnostica Senese S.p.A.

It is also possible to set availability of each sample in the Service menu during installation, further to the client's request.

The **Pending database** (fig. 3.2.j) stores:

1) The samples already processed that have not yet received authorisation from the host to execute their analysis. The results of these samples cannot be displayed. The presence of a sample in this database is limited to 72 hours (the date/time field of the sample itself is considered as the beginning), after which all information about the sample will be removed. The device, during the stand-by period, will try to communicate with the host to know which pending samples must be saved and rendered available to the operator and which ones must be removed.
2) Samples with bar codes that were unable to be read will also be inserted into this archive; in this case the operator must open the Pending archive to insert the missing codes (this can be done with the external bar code reader or manually with the virtual Windows CE keyboard). This way the devices will be able to ask authorisation to the host also for these samples.

The operator can force the authorisation for one or more samples manually; select the sample/s and push “Send to host”. This forcing manoeuvre determines the passing of the data regarding the sample to the host, the move of them from the pending archive to the historical archive and the decrease of the test counter of the check device. (see paragraph 3.3)

If the instrument works without a host connection in this archive the samples where the barcode was unable to be read will be present. Opening the pending archive, the position in the sample holder rack and the result of the ESR will be displayed for these samples. The relative missing codes must be inserted by the operator using the external barcode reader or manually with the virtual Windows CE keyboard, as indicated in the paragraph “Description of the commands and the information in the pending archive mode”.

The **Quality Check database** (fig. 3.2.k) contains the historic data regarding the results of the “ESR Control” samples; this database has an autonomic management regarding the other archives.

Description of the commands and information in Historical archive mode

fig. 3.2.i

Show All (List all): all samples present in the historical archive of the database are listed.
FIND: equals an “enter”, has the function of sample search based on the code number.
FIND: equals an “enter”, has the function of sample search based on the date.
From [dd/mm/yy] to [dd/mm/yy]: the automatic presence of the current day facilitates the search of samples analysed on that date. To search for samples analysed in other days it is necessary to insert in the corresponding range in which one wants to execute the search, or us the code search field.
Select all: immediate selection of all present samples.
De-select all: immediate de-selection of all present samples.
Send to host: sends the sample(s), selected by means of the checkbox, to the host
Eliminate: eliminates the sample(s) selected
Print: print the list of the samples that are selected by means of the check box
Arrow UP: executes multiple selections of samples by scrolling the list up the list
Arrow Down: executes multiple selection of samples by scrolling down the list
Exit: returns to the main menu

In addition to the buttons described in the previous paragraph, there is additional information available:
Number of records in the archive: total number of samples present in the quality archive of the database
Number of records in the list: total number of samples present in the list that is displayed.
Error key: interpretation of the letters indicated in an error code.

The following is also visible on the display screen:
Code: code of the sample and relative check box to allow the selection of that sample
Host: if an [*] is present near the alphanumeric identification code of the sample, this means the sample is already sent to the host.
Date: date of analysis
Time: time of analysis
ESR: VES result (if it is 0 it means that the sample data has not been analysed on the host's request, but availability is active).
Errors: error code
Rack ID: identification of the sample holder rack.
R Pos: position in the sample holder rack (identified by an alphanumeric code)

Description of the commands and the information in pending archive mode

The samples defined as "PENDING" refer to all those results that have not been downloaded to the host computer (for example; because of temporary absence of connection) or that are not present in the historical archive.


ATTENTION

1. As a reminder, a **PENDING** sample, if the instrument is connected to a host, does not display the **ESR** results
2. Every time the Ves-Matic Cube 80 sends a result to the host and/or the historical archive the counter of the executable test is decreased (visible on the Check Device window in the View Analysis Mod. and the View Preparer Mod.)

fig. 3.2.j

Show All (List all): lists all samples present in the Pending archive of the database
FIND: search function of samples based on barcode or date
Select all: immediate selection of all present samples.
De-select all: immediate de-selection of all present samples
Update code: allows the input of a barcode by means of the Windows CE keyboard, in the case it is not read automatically by the instrument, the keyboard will appear automatically inserting the desired bar code into the field above this command.
Read bar code: allows the input of a bar code by means of the external bar code reader, in the case it is not read by the reader inside the instrument
Send to host: sends the sample(s), selected by means of the checkbox, to the host
Eliminate: eliminates the sample(s) selected
Arrow Up: executes multiple selections of samples by scrolling up the list
Arrow Down: executes multiple selection of samples by scrolling down the list
Exit: returns to the main menu

In addition to the buttons described in the previous paragraph, the following information is presented:
Number of records in the archive: total number of samples present in the Pending archive of the database
Number of records in the list: total number of samples present in the list that is displayed.
Error key: interpretation of the letters indicated in an error code.

Furthermore the following is also visible on the display screen:

Code: barcode of the sample

Date: date of analysis

Time: time of analysis

Rack ID: identification of the sample holder rack.

R Pos: position in the sample holder rack (identified by an alphanumeric code)

Description of the commands and information in Quality Check archive mode

ATTENTION: As a reminder, a **QUALITY** control sample is managed in a different manner

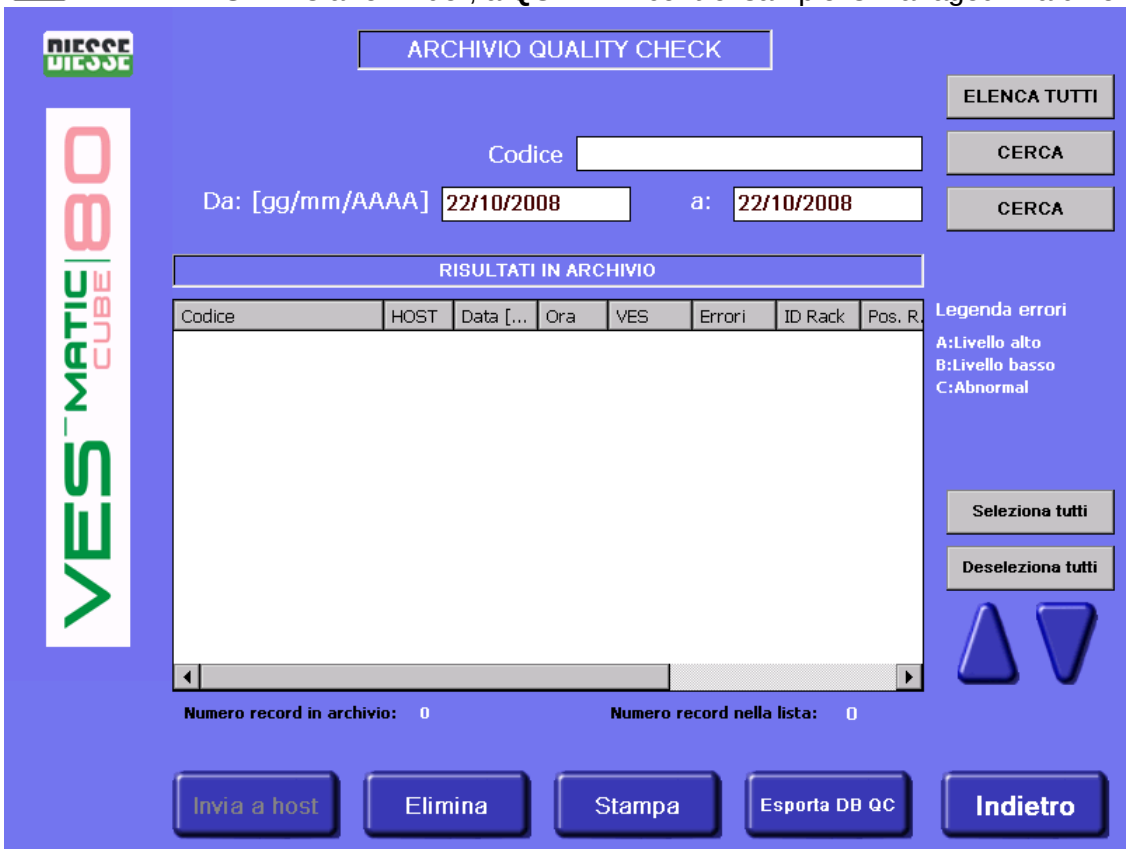


fig. 3.2.k

Show All (List all): lists all samples present in the database of the Quality check archive

FIND: search function of samples based on barcode or date

Select all: immediate selection of all present samples.

De-select all: immediate de-selection of all present samples

Send to host: sends the selected sample(s) to the host

Eliminate: eliminates the sample(s) selected

Print: print the list of the samples that are selected by means of the check box

Export DB QC: allows export of the Database of the QC archive in text format

Arrow Up: executes multiple selections of samples by scrolling up the list

Arrow Down: executes multiple selection of samples by scrolling down the list

Exit: returns to the main menu

In addition to the buttons described in the previous paragraph, the following information is presented:

Number of records in the archive: total number of samples present in the quality archive of the database

Number of records in the list: total number of samples present in the list that is displayed.

Error legend: interpretation of the letters indicated in an error code.

Furthermore the following is also visible on the display screen:

Code: barcode of the sample

Host: if an [*] is present near the alphanumeric identification code of the sample, this means the sample is already sent to the host.

Date: date of analysis

Time: time of analysis

ESR: ESR result

Errors: error code

Rack ID: identification of the sample holder rack.

R Pos: Position of sample in the sample holder rack (identified by an alphanumeric code)

Batch num: the lot number of the QC sample.

Exp date: expiry date of the QC sample

Min Val: the minimum value obtainable with the QC sample

Max Val: the maximum value obtainable with the QC sample

3.2.3 Setup Menu

Description of the commands and information of the Setup menu

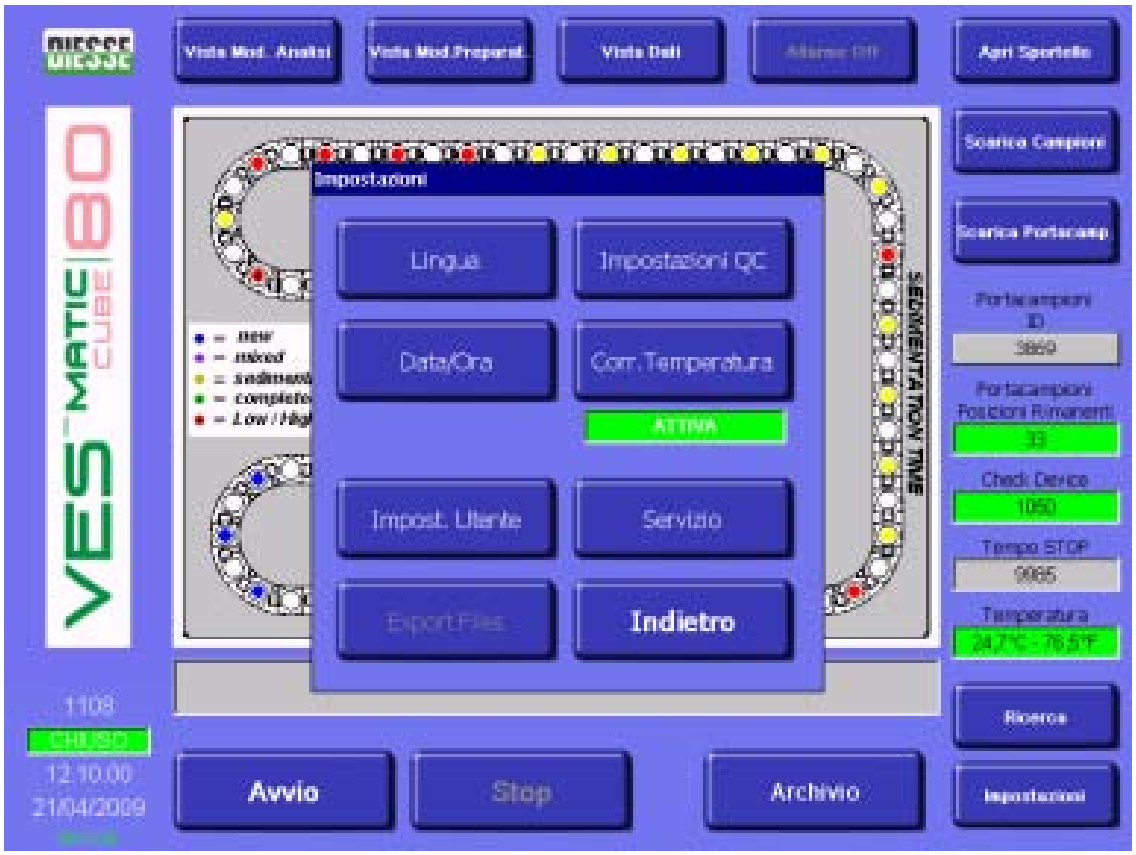


fig. 3.2.l

This function allows access to some update and service procedures (fig. 3.2.l):
Language, QC Setting, SW Update, Date/time, Temperature Correction, User Settings, Service

Language allows the language to be selected; in fact, by typing this command, the following window appears: Select language (fig. 3.2.m). To set the selected language in the instrument, press the corresponding button on the display.

fig. 3.2.m

QC settings (Quality control) (fig. 3.2.n)

The quality control settings window allows the set-up of all parameters for the QC samples, so that the Ves-Matic Cube 80 can recognise them and store them separate to the normal samples.

To set-up any QC parameter select, by touching it, one of the available white fields (bar code, lot number, expiration date, minimum value, maximum value); immediately the virtual Windows CE keyboard will appear for the input of the values. To delete possible input errors it is sufficient to position on the right of the character that must be deleted and use the “BS” (Rear Space) button, which allows deleting a character at a time.

EXPLANATION OF EACH SECTION :

Normal level: *area reserved for the QC parameters for a normal ESR value (refer to the technical instructions supplied with the control sample)*

Abnormal level: *area reserved for the QC parameters for abnormal/pathological ESR value (refer to the technical instructions supplied with the control sample)*

EXPLANATION OF THE FIELDS:

Bar code: insert bar code present on the test tube(s) of the QC sample(s)

Batch num: insert the batch number of the QC sample, traceable on the package.

Expiration date: insert expiry date of the QC sample, traceable on the package

Min. Value: insert the minimum value obtainable with the QC sample, traceable in the technical instructions
Max. Value: insert the maximum value obtainable with the QC sample, traceable in the technical instructions

COMMANDS in the Quality Control set-up window:
Confirm: saves the data inserted and/or modified
Rear: returns to the main menu (that is "SET UP")

fig. 3.2.n

Select one of the available white fields to set-up any parameter; the virtual Windows CE keyboard will appear immediately for the input of the values. To delete possible input errors it is sufficient to position on the right of the character that must be deleted and use the "BS" (Rear Space) button, which allows the deletion of a character at a time.
To complete the information on the Quality Control please read paragraph 3.4. of this manual and the technical instructions supplied with the control sample.

Date/time: allows the select the format of the date and to set Date and Time of the system. Pressing this button the **Set Date/Time** window will appear. (fig. 3.2.o)

EXPLANATION OF EACH SECTION :
Date:
Set up date format
DD/MM/YYYY: format with day/month/year
MM/DD/YYYY: format with month/day/year
To complete the selection of the date format, confirm the operation using the specific "confirm" button, return to "View Analysis Module", turn off and turn back on the main instrument switch. After this operation the date will be displayed in the selected format.

Set-up of the Date
EXPLANATION OF THE FIELDS:
DD: set-up the day, using the buttons + and -
MM: set-up the month using the buttons + and –
YYYY: set-up the year using the buttons + and -

Time: set-up time
EXPLANATION OF THE FIELDS:
HH: set the hour of the day using the buttons + and -
MM: set the minutes using the buttons + and -
SS: set the seconds using the buttons + and -

COMMANDS of the Set-up Date/Time window:

Confirm**:** saves the data inserted or modified

Rear**:** returns to the MAIN menu (that is “SET UP”)

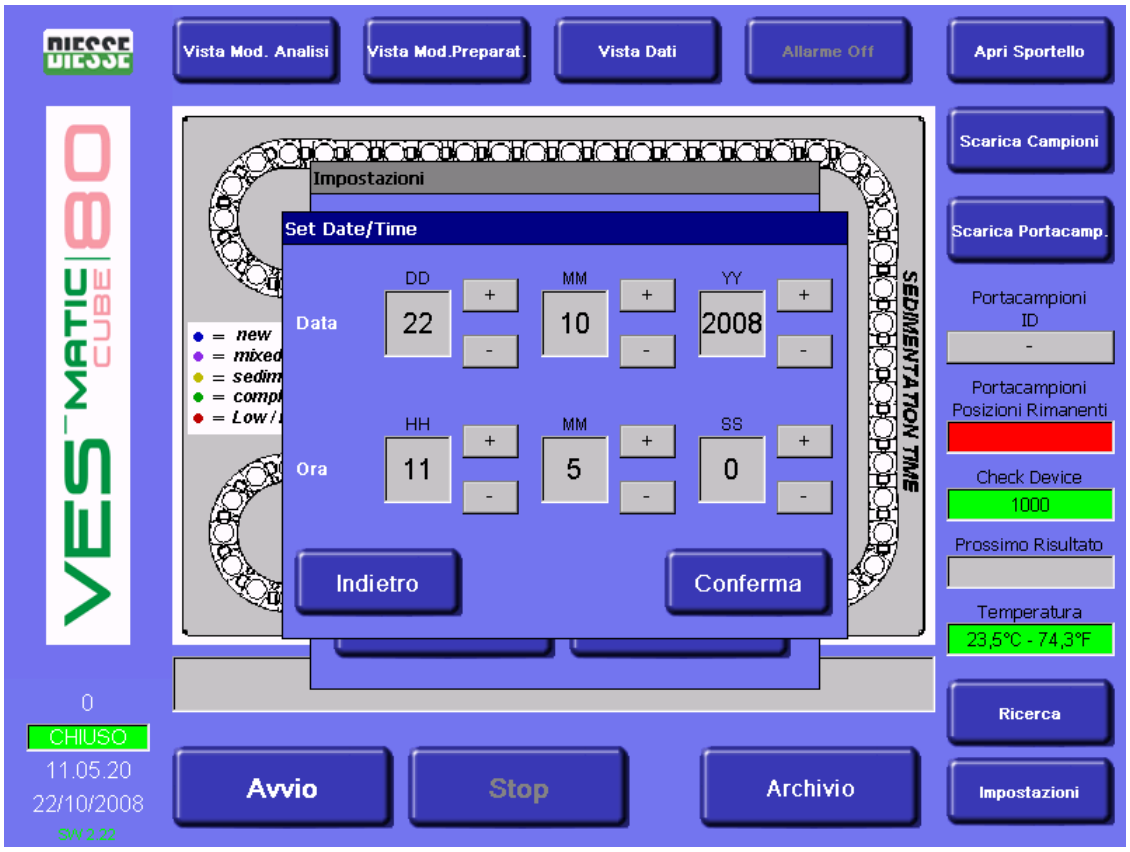


fig. 3.2.o

Temperature corr.: allows the activation/deactivation of the automatic temperature correction of the results (when the automatic correction of the temperature is activated the relative window is coloured green and displays the writing ‘ACTIVE’, when it is deactivated the window is red and shows the writing ‘DEACTIVATED’)

User settings (fig. 3.2.p)

DESCRIPTION OF THE FIELDS

ESR MAX VAL: This field allows the user, based on specific needs, to set up the ESR value (“ESR MAX VAL”) beyond which one desires to repeat a new analytic cycle (“RETRY”). All samples with ESR results higher than the inserted value, will be automatically re-analysed.

MAX NUM RETRY: This field allows setting the number of repetitions of the analytic cycle (“MAX NUM RETRY”) regarding those samples which ESR is higher than the set value; the maximum number of sample repetitions is three.

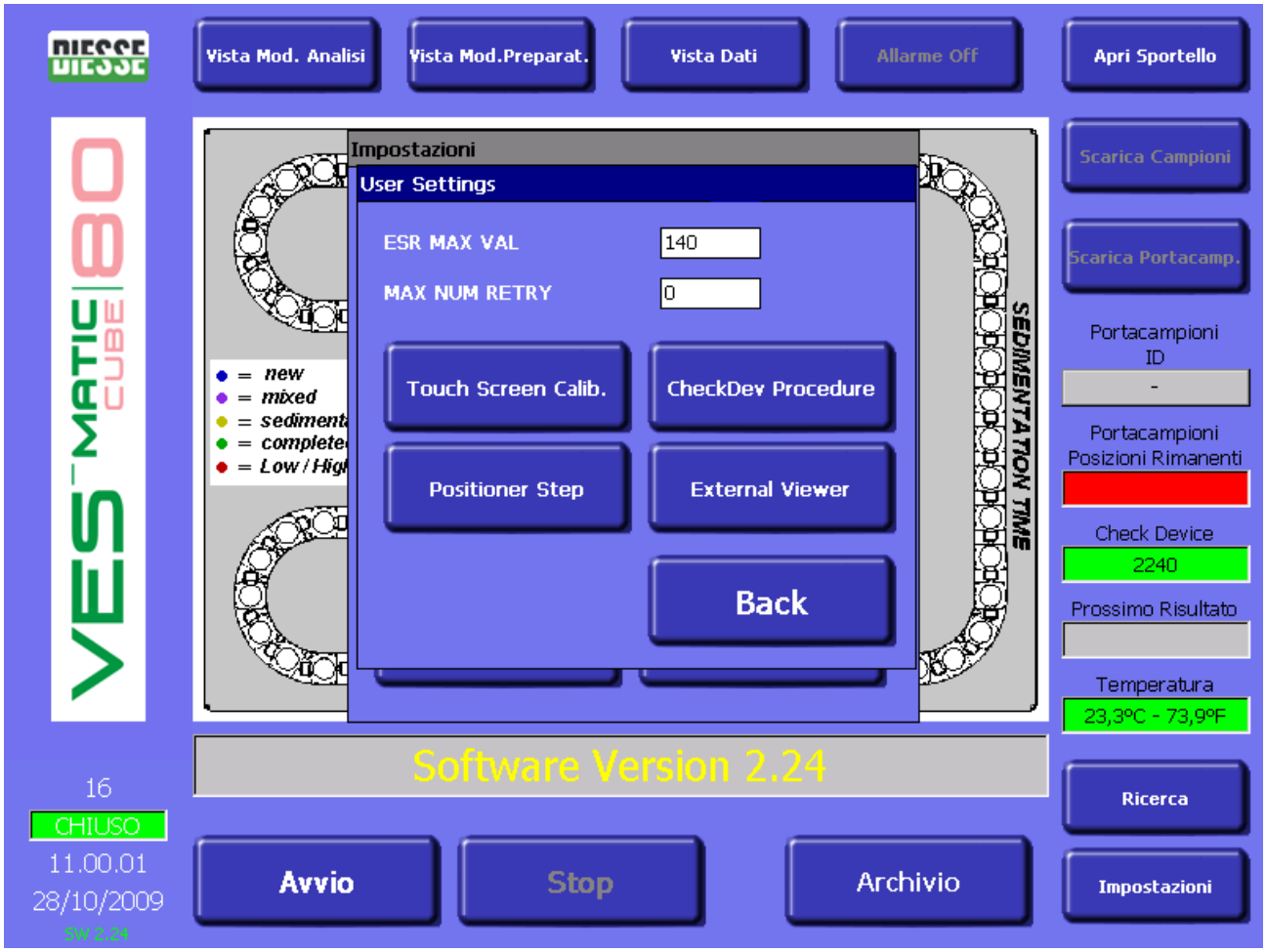


fig.3.2.p

DESCRIPTION OF THE FIELDS

Touch screen calibration: pressing this button allows temporary adjustment, of the calibration of the tabled PC. The procedure to follow is guided and at the end of it the new “User settings” will appear. The obtained calibration is only temporary and will be lost at the switch off of the analyser by the main switch.

Positioner step: this command, which should be used by expert operators only and allows rapid retrieval of a test tube from the analytical chain. After opening the front panel of the instrument and inserting the appropriate micro switch key to avoid a complete stop, it is possible to determine, by pressing the button several times the advancement of the desired test tube up to the point in which manual access for the removal of it is allowed.

Check Dev Procedure: This button allows you to initiate the recharge of the check device (see section 3.3)

External Viewer: pressing this button starts up the Acrobat Reader programme with which it will be possible to open the pdf files as the user manual.

Rear: returns to the MAIN menu (that is “SET UP”)

Export Files: pressing this button allows for copying the following files on the SD card (external memory): COUNTERS (INI.File), ERRORLOG (TXT.File), EVENTS (TXT.File), LOG (TXT.File),

Vescube (DB.File),Vescube (INI.File). The procedure is the following: insert the compact flash card in the relative slot, as shown in the figure 3.2.q, the button “Export Files” will activate, illuminating the command in white, then press the button and await the end of operation before removing the SD card.

Fig. 3.2.q

Service: allows access, by means of a password, to the service menu of the instrument.

Only personnel authorised by DIESSE Diagnostica Senese S.p.A. are permitted to access this function.

Rear:

Allows return to the MAIN MENU (that is “SETUP”)

3.3 CHECK DEVICE

The “check device” is an electronic device that allows the instrument to have a defined number of executable tests available. For every result the check device will automatically undergo a decrease of the number of available tests. Once the number of tests is exhausted, it is necessary to reload the instrument using the special “Check Device Transponder RF” test tube (fig. 3.3.a) (see paragraph 1.3:) The test tube has the dimensions and appearance of a normal one.

fig. 3.3 a
“Check Device Transponter RF” test tube

To reload it is necessary to open the door. This will allow access to the check device reloading device to the left of the mixing unit (see figure 3.3b).
Then insert the “Check Device Transponder RF” inside the device (see figure 3.3c).

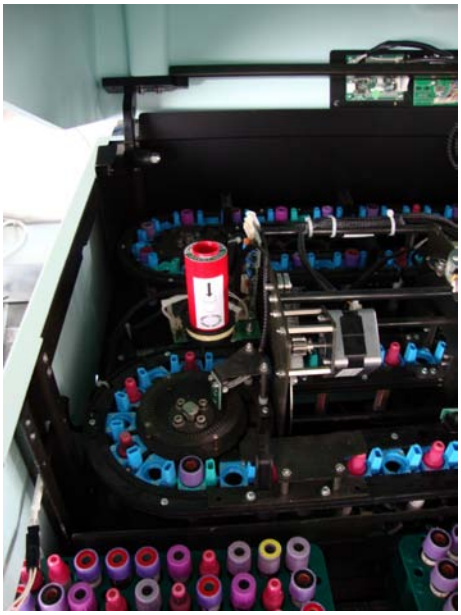


fig. 3.3 b

fig. 3.3 c

After placing the “Check Device Transponder RF” test tube in the slot, choose the **Check Dev Procedure** in the user settings (fig 3.2.p). After a delay of a few seconds a message will appear in the dialog bar: “Refill check device conducted” if the outcome of the recharge is positive, “Error in refill check device” in the case of a negative result (in this case it is advisable that the operator retrieves the “Check Device Transponder RF” test tube and repeats the operation from the beginning).

At the end of the procedure the “Check Device Transponder RF” test tube is empty and cannot be reused. It should be retrieved from the slot and disposed of in accordance with current legislation.

Functioning of the check device:

A. When the result of a sample is saved on the historical database, and possibly printed, the counter of the check device is decreased.

B. If the instrument works without a host connection all results are saved on the historical database, printed, displayed and the counter of the check device is decreased for each one. The results regarding samples with a illegible bar code are saved in the pending archive (see Pending Archive in 3.2.2)

C. If the instrument is configured to work connected to a host, only the samples for which the host computer has requested an analysis will be analysed, then the results are printed, displayed, saved on the historical archive and sent to the host and, consequently, the counter of the check device is decreased. All the others will not be analysed, however, if a request for sample traceability is made, the unanalysed samples will be shown in the printout, in the archive and on the host (which will obviously not decrease the test counter).

D. In the case of a temporary absence of a host connection, the instruments proceeds as follows:
   1. The test tubes will all be processed and the data saved temporarily (72 hours) in the Pending database. The data of these test tubes is all displayed, except the analytical result.
   2. At the time of the positioning of the test tube in the sample holder rack only the barcode and the position of the test tube in the sample holder rack will be printed, the result of the analysis will not be printed.
   3. At the end of the analytical cycle the instrument, at regular intervals and for a maximum of 72 hours, will continue to interview the host to establish which pending samples already analysed were actually requested.
   4. The results regarding the test tubes requested by the host are transferred and saved in the historical archive and sent to the host. The counter of the check device will be decreased in consequence. The results of the samples not requested by the host will be removed from the Pending database.
   5. If it is not possible to re-activate the connection with the host, the operator can enter the Pending archive and manually force the acceptance of one or more samples, the data of which must be printed right away, sent to the host (if possible) and saved in the historical archive. The check device test counter will be decreased.
   6. After a period of 72 hours in the Pending archive the data of the sample test tubes will be removed.
   7. If, caused by a lack of connection to the host, the instrument is unable to send the results of the accepted test tubes, they are copied and memorised in the historical archive. The instrument will try cyclically to send them to the host for 72 hours, after which the data is only available in the historical archive.
   8. The operator can re-send the data of one or more samples in the historical database to the host. In this case the instrument will try cyclically to send the data of those samples to the host for a maximum of 72 hours.

E. If the number of executable tests finishes during the analytical activity the instrument will save, for 72 hours and in a virtual archive, all data regarding the analysed samples (up to a

maximum of 3.000 items), the relative results will not be displayed until the test counter is reloaded. This temporary saving (72 hours) allows analyses to be completed, the data on analysed samples not to be lost and therefore to avoid repeating the analysis and provide the laboratory enough time to organise a new transponder to reload the test counter. The number of the tests available in the instrument is indicated in the dedicated window (fig. 3.2.b), its colour informs the user of the remaining tests available; green indicates the possibility of analysing more than 1000 tests, orange indicates that the number of available tests is between 500 and 1000, yellow indicates that the tests available are less than 500, while the red indicates the number of executable tests is exhausted.

3.4 GUIDED READING OF THE RESULTS PRINTOUT

The Ves-Matic Cube 80 prints the results of each sample in real time.

The printout complete with header of the results regarding the samples in a sample holder rack (classifier) is obtained in two cases:

1) when the sample holder rack (classifier) is complete. In this case the instrument will slide the sample holder rack automatically up to the exit, positioned at the lower left side of the instrument (fig. 2.2.2); from this position it is possible to extract the sample holder rack completely. At the same time the printer will complete the printout of the results of the samples in that sample rack holder that will appear as described in fig. 3.4.a and 3.4.b.
2) When, at the end of the day the analytical routine is completed and after having pressed the "Stop" button, in this case the sequence of operations is the following: pressing the "Stop" button, activation and pressing the "Unload sample holder" which allows the sample holder rack to slide to the exit and the printout of the results regarding the samples contained in that sample holder rack, which will appear as described in fig. 3.4.a.
3) When the samples to be analysed in the sample holder rack (classifier) have been completed and there is a new rack queuing up, in this case, the conveyor belt will move the sample holder to the exit of the Ves Cube and the printer will end the data printout on the classifier rack ,as described in figures 3.4a and 3.4b.

In any case, a header will appear displaying, in this order: the name of DIESSE, the name of the instrument, the software release (V. X.xx), the writing of "EDTA" for results expressed in Westergren EDTA/1h units or no specification for results expressed in Westergren citrate/1h units (see figs. 3.4.a and 3.4.b) depending on the set-up selected in the laboratory at the time of installation (see paragraph 1.1), the serial number of the instrument (SN), the temperature detected inside the instrument (in °C – °F), the correction of the temperature (active = 'ON', not active = 'OFF'), the date (DD/MM/YYYY or MM/DD/YYYY, see paragraph 1.1) and the time (HH/MM/SS) of the execution of the analyses, the barcodes, the corresponding ESR value (if the ESR value does not appear on the printout this means that the sample has not been analysed or that it is in the pending archive) and the position of the sample in the sample holder rack (classifier) identified by a alphanumeric code (POS NUM). At the end of the list of samples and their related data (the barcode of the sample holder rack (COD SAMPLE HOLDER) will appear.

When a control sample is analysed (see paragraph 3.2) the results printout shows the following: (fig. 3.4.a): QC PASS xx/xx, N. Lot xxxx, Expiry date DD/MM/YY, xxxxxxx (QC barcode) the ESR value reading for that control sample and its position in the sample holder rack. To evaluate the obtained result refer to the technical instructions supplied with the control sample.

```
* * * * * * * * * * * * * * * * * * * * * * *
          DIESSE S. p. A
* * * * * * * * * * * * * * * * * * * * * * *
          VES MATIC CUBE 80 V. 2.23

SN: 2007- 01- 00XX
TEMPERATURE : XX°C – XX°F
TEMPERATURE CORRECTION : ON
DATE : DD/MM/YYYY ( MM/DD/YYYY)
TIME : HH/MM/SS

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

  ID                          WEST        POS
BarCode                       1H          NUM

 QC PASS                  1/12

 N.  Lotto     xxxxx      Scadenza    :   DD/MM/YYYY
 QC ID Bar Code                  5            C1
 QC PASS                  38/64

 N.  Lotto     xxxxx      Scadenza    :   DD/MM/YYYY
 QC ID Bar Code                 45            B8
 53435661                       57            B7
 90087006                        6            B6
 99887788                       43            B5
 65432211                        9            B4
 65443297                       17            B3
 43325544                     HIGH            B2
 76554888                       29            B1
 65334567                      LOW            A8
 53435661                       55            A7
 90087006                        5            A6
 99887788                      ERR            A5
 65432211                       10            A4
 ……                             19            A3
 44332255                       14            A2
 53435543                       43*           A1
COD. PORTACAMPIONI :  1234
```

fig. 3.4 a

```
* * * * * * * * * * * * * * * * * * * * * * *
          DIESSE S. p. A
* * * * * * * * * * * * * * * * * * * * * * *
          VES MATIC CUBE 80 V. 2.23
                    ED TA
SN: 2007- 01- 00XX
TEMPERATURE : XX°C – XX°F
TEMPERATURE CORRECTION : ON
DATE : DD/MM/YYYY ( MM/DD/YYYY)
TIME : HH/MM/SS

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

  ID                          WEST        POS
BarCode                       1H          NUM

 QC PASS                  15/28

 N.  Lotto     xxxxx      Scadenza    :   DD/MM/YYYY
 QC ID Bar Code                 20            C1
 QC PASS                  58/88

 N.  Lotto     xxxxx      Scadenza    :   DD/MM/YYYY
 QC ID Bar Code                 66            B8
 53435661                       80            B7
 90087006                       21            B6
 99887788                       64            B5
 65432211                       24            B4
 65443297                       34            B3
 43325544                     HIGH            B2
 76554888                       47            B1
 65334567                      LOW            A8
 53435661                       78            A7
 90087006                       20            A6
 99887788                      ERR            A5
 65432211                       26            A4
 ……                             36            A3
 44332255                       30            A2
 53435543                       64*           A1
COD. PORTACAMPIONI:  4321
```

Fig. 3.4.b the modality of expression of the results is highlighted in the red circle , according to the Westergren EDTA manual method (mm/h/EDTA)

When a sequence of points in the “ID BarCode” column appears this means that the internal barcode reader did not read that barcode, for that sample, the position of which is indicated in the respective sample holder rack, but was analysed anyway (in the example of fig. 3.4.a, the result is displayed in B1 because there is no host connection active; in the case of an active host connection, see the description in 3.2.2 “Archive Menu”); the data regarding this sample is stored in the Pending Archive. At this point the operator can continue as described in 3.2.2 “Archive Menu: Historic DB and Pending DB”.

The following messages may be shown in the “WEST 1H” column (referring to the results expressed in Westergren citrate units as well as those expressed in Westergren EDTA units):
“ERR”: means that the instrument has not been able to reveal any “characteristic point” useful for the readings, thus it is advisable to check the sample and, after excluding labelling problems, clots, etc. to repeat the analysis.
“LOW”: means that the quality of blood of the sample is insufficient (≤ than 1.5 ml). Verify the level of the sample, should this be lower than 1.5 ml, repeat the blood sample.
“HIGH”: means that the quantity of blood of the sample is excessive (> 4 ml). Verify that an air space exists between the end of the cap and the sample level. If the level of the test tube is in fact excessive, remove, after mixing, about 500 µl of blood and repeat the test.
“xx*”: value of ESR with an asterisk (for example “43*” as in fig. 3.4.a) means that the instrument has read a value, but advises the operator that the state of the sample does not correspond to that specified in 4.2.2 (figs. 4.2.2a, 4.2.2.b, 4.2.2.c). The operator is advised to check the sample to exclude labelling problems , clots, etc., and decide whether to validate the obtained result or to repeat the analysis.

HIGH	Verify that an air space exists between the end of the cap and the level of the sample. If the level in the test tube is in fact excessive, remove, after mixing, about 500uL of blood and repeat the test.
Test Tube with sample level too high: exceeds 4 ml.	
LOW	Verify the level of the sample. Should this be under 1.5 ml, repeat the blood sample.
Sample test tube with sample level too low: less than 1.5 ml.	

4 CHAPTER 4

4.1 GENERIC DESCRIPTION OF AN ESR ANALYTIC CYCLE IN THE VES CUBE 80

ESR Erythrocyte sedimentation rate 1h.
This supplies the results in accordance with the Westergren citrate method with a reading after one hour; the overall duration of the **analysis** for the first sample is **24 minutes** then the results come out every **38 seconds**.

Description of the test cycle:

- At the beginning of the analysis, the unit queries the sensor underneath the rack pulling unit and checks that there is a sample holder present. If not, insertion will be requested on the information bar, and it is then pulled first under the sensors that will check the presence and location of the first samples and then to the optimum position for allowing the pincers to draw out the test tubes.
- At this point, the samples are withdrawn by the pincers and placed in front of the barcode reader, the samples will be turned round until the barcode can be read by the reader.
- After the barcode reading a host query for each sample is conducted (if there is a connection with a host), to recognise if the identified sample requires an ESR analysis.
- After recognising the sample, the samples for which an ESR analysis has been requested will be introduced into the chain, otherwise they will be placed back on the rack.
- The samples for ESR are inserted one by one in the underlying chain of the analysis module and moved, with a step time of 19 secs, to the mixing zone. On entering the mixing zone, every sample is rotated by 120°, 3 times every step, so after 5 steps inside the mixing zone every sample has been mixed 15 times.
- At the exit from the mixing zone, the instrument will execute the first reading for the determination of the total blood level in the sample.
- Every test tube is then moved with a step time of 19secs to the second sensor (overall time of 20 mins)
- The instrument then executes a second reading, for the determination of the level of the red blood cells after the sedimentation, all data is processed and the ESR results are

reported in Westergren citrate units or Westergren EDTA units, depending on the set-up selected by the laboratory at the time of installation (see paragraph 1.1).

- The analysed test tubes are removed one by one from the chain, by means of an ejection system and positioned in the green area of the sample holder rack in positions identified by alphanumeric co-ordinates.

4.2 DETAILED DESCRIPTION

4.2.1 Initial power up

After the installation of the instrument as indicated in chapter 2, ensure that the window is closed and press the power switch, situated on the left of the power cable on the back of the instrument, into the ON position <<**I**>>

At the first power up, to verify the status of the instrument and the efficiency of the Optical Reading Group, the following is advised:

- Introduce the Normal and Abnormal ESR quality control blood in two separate test tubes normally used in the laboratory, position them in the racks and start an analytic cycle. At the end of the test verify that the results obtained correspond to the expected values (*refer to in the content of the technical instructions supplied with the ESR Quality Control package*)

Attention: The blood contained in both the Normal and Abnormal ESR is an artificial control blood with particular characteristics, such as consistent and resistant “compression”. Thus, to obtain the fluidity necessary to execute a correct control test it is necessary to mix the samples for a long time and very thoroughly. It is also important that the control blood, at the moment of the examination, is at room temperature.

Quality Control Test

The performance of the Ves-Matic Cube 80 instrument is verifiable at any moment using the ESR Quality Control.
The ESR Quality Control constitutes a stable material that allows the determination of the precision of the Ves-Matic Cube 80 and of the total Ves-Matic line for measurement of the erythrocyte sedimentation rate.
The expected values, dependent on instrument type, are reported on the illustrative page inside the ESR Quality Control pack (see paragraph 0*)*

For the conservation, the preparation and use of the control blood refer to the illustrative page inside the packaging of the control blood.

4.2.2 Preparation of the sample

No special preparation of the test tubes is required, since the Ves-Matic Cube 80 uses the test tubes from the haematology analyser (CBC examination); it is advisable none the less to comply with the guidelines related by the ICSH, of which we cite the most important ones:

- *The blood should be obtained by means of a withdrawal of the maximum duration of 30 seconds and without excessive venous stagnation.*
- *The blood can be gathered in both vacuum test tubes with EDTA as well as non-vacuum test tubes with EDTA. It is recalled that the Ves-Matic Cube 80 uses the test tubes directly from the blood cell counter.*
- *Mix the blood immediately after the withdrawal with at least 2 complete inversions of the test tube.*

Suitability of the sample

The sample can be considered suitable when:

- the test is conducted within 4 hours of the withdrawal
- the test is conducted on a blood sample conserved at 4° for a maximum period of 24 hours. In this case ensure that the sample is at room temperature before inserting it into the instrument for the analytic cycle.
- always turn the test tube upside down before inserting it into the instrument (Attention: during this manoeuvre ensure no clots are present.

ATTENTION: Verify that the test tube is **hermetically** closed

Filling of the test tube

The level of blood in the test tube is fundamental for the correct conduct of the ESR examination by the Ves-Matic Cube 80 instrument.. The instrument itself will verify the correct filling of the test tube, measuring the level and comparing it with the pre-set tolerance values of maximum and minimum level.

In the case of excessive (over 4.0 ml) or insufficient filling (less than 1.5 ml) the instrument will print an error message. If the filling is excessive, it signals "HIGH", if the filling is insufficient it signals "LOW". In both cases the analysis must be repeated with the correct quantity of blood. The same message will appear on the results printout

Check of test tube labelling

Sample labelling method and compatibility with the number of labels

Ves Matic Cube 80 models are designed to work with a maximum of two labels, not overlapping, attached to the same test tube to be analysed. (Fig. 4.2.2.a).

The internal barcode reader, inside the preparer module, is mechanically regulated to work with labels applied to the sample at least 3 mm above the rounded bottom of the test tube Fig. 4.2.2

a①); it is also programmed to read barcodes placed at 90° from the reading band, i.e., with the code perpendicular to the longitudinal axis of the test tube Fig. 4.2.2 a ②). The reader nevertheless can correctly read sloping barcodes (corrected) by + 5" (fig. 4.2.2.a ③).

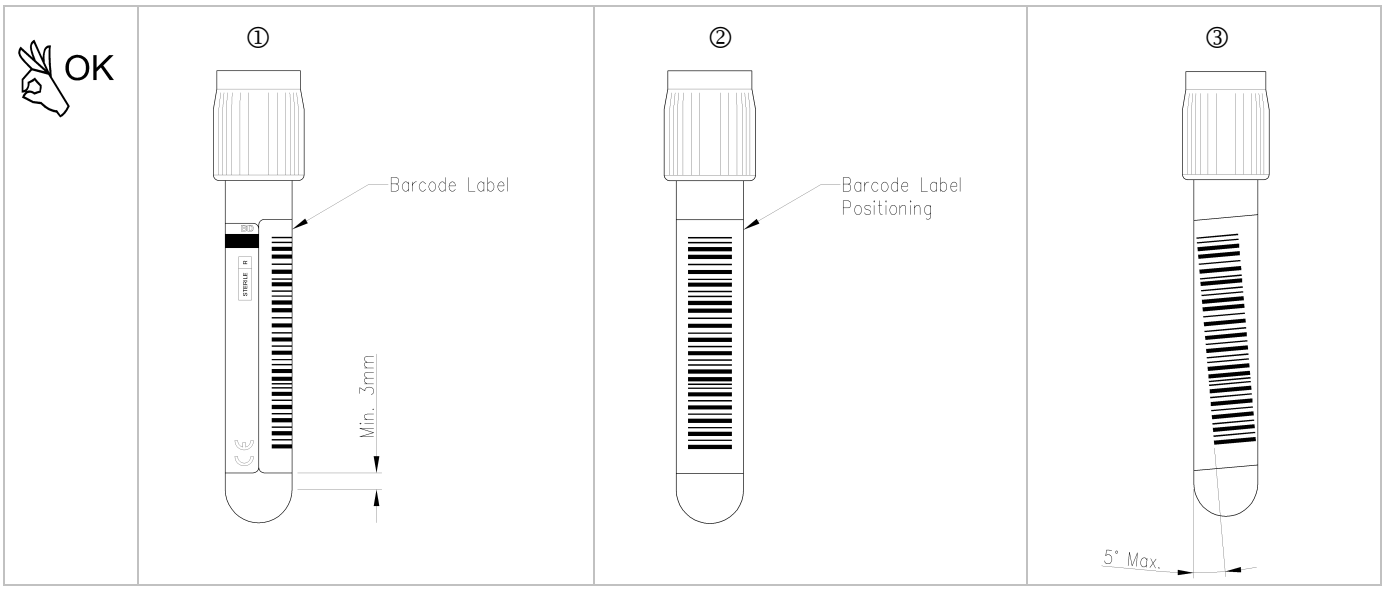


Fig. 4.2.2.a Correct height of application of the label on the test tube

The reading group sensors are able to detect correctly the sedimentation rate inside each sample, following the reading axis, reading through a maximum of three layers of paper: Thus only two labels at most are attached to the test tube which must be staggered with each other by least 90° degrees (fig. 4.2.2.b).

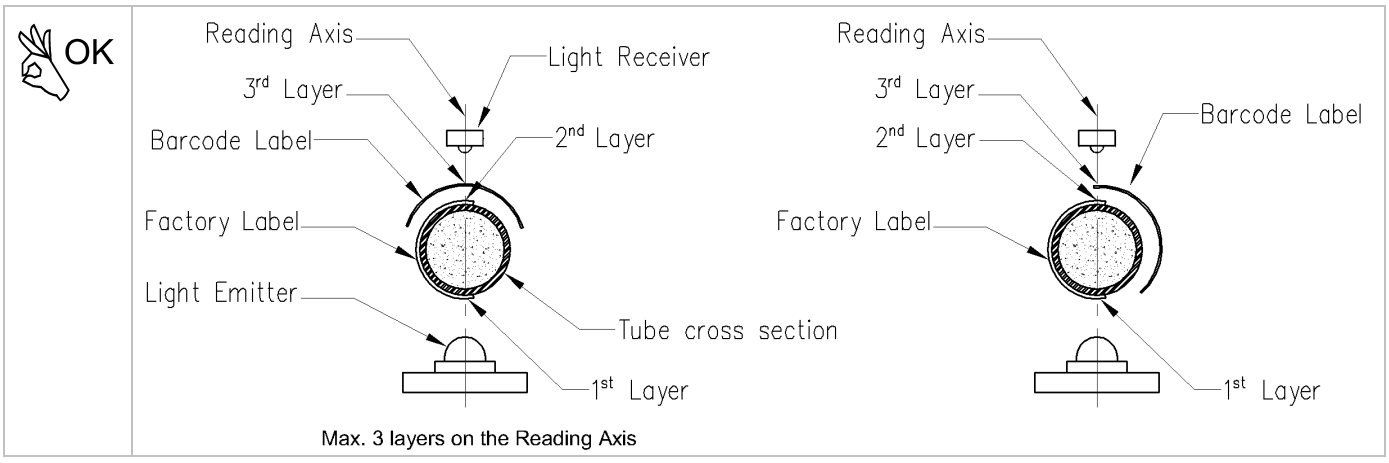


Fig.4.2.2 b Maximum number of label layers attached to test tube and accepted by the Ves Matic Cube 200'

It is important to verify, before loading the instrument, that the labels adhere perfectly to the test tubes: the adhesive parts, if detached, can cause frictions during the mechanical movements of the groups (inserter, ejector, and sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.

In fig. 4.2.2c some "INCORRECT" labelling examples are displayed, which are potential causes of mechanical blocks and/or reading problems on the Optic-Electronic Sensors.

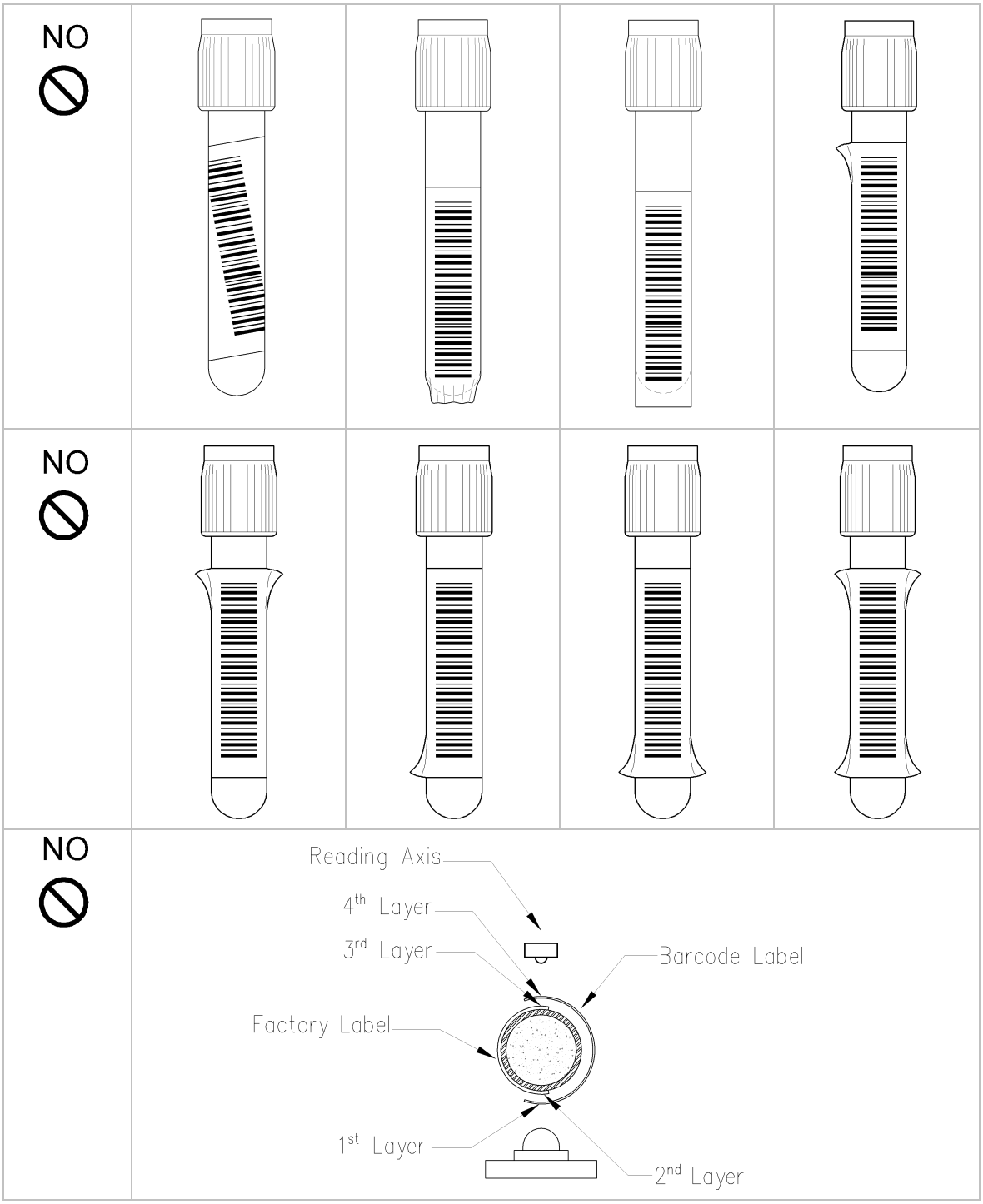


Fig.4.2.2.c INCORRECT sample labelling modes

4.2.3 Warnings and limitations

Insert the samples to be analysed in the red area only of the sample holder rack and insert the rack in the right side of the ves-cube, along the extension (see photo)

fig.4.2.3.a

fig.4.2.3.b left side

fig.4.2.3.c right side

There is a rack loading extension on the left side of the instrument for the exiting sample holder racks containing the analysed samples (fig. 4.2.3.b). The sample holder rack slides from right to left.

Do not switch off the instrument during the working phases or during the Reset procedure.

The machine must be turned off ONLY after pressing the STOP button on the display
and waiting for the movement to end.

ATTENTION

	If an analysis is carried out using just a few samples, it is worthwhile filling the free rows to the left of the rack, in the red area only.
	Do not switch off the instrument during the working phases or during the Reset procedure. To safeguard the database it is advisable that the instrument is turned off **ONLY after pushing the STOP button** on the display and awaiting the completion of the movement.

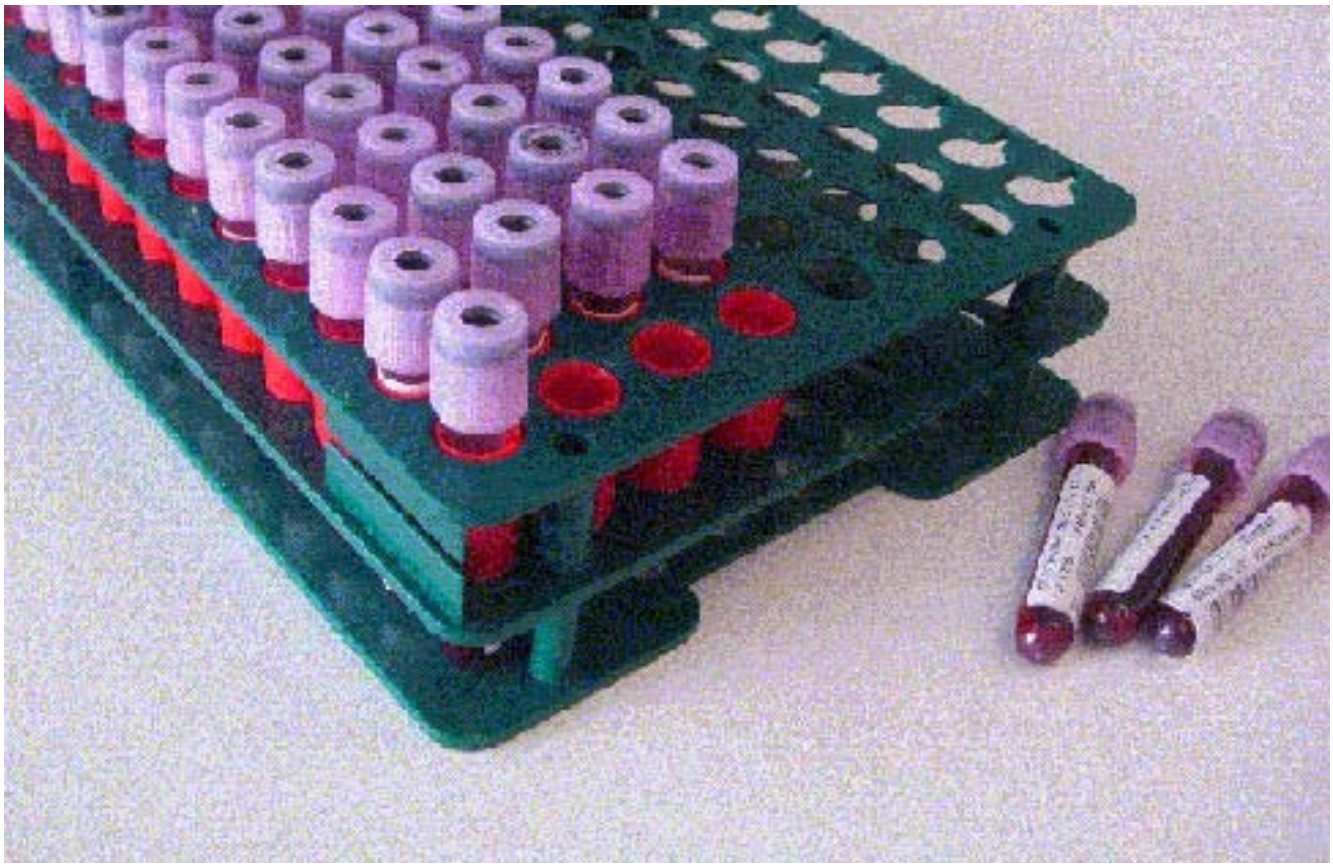


fig. 4.2.4.a

4.2.4 Preparation sequence for a test

Loading procedure of the samples:

a. Press the START button, wait for the Reset to be completed.
b. Insert the rack in its housing (visible in fig. 4.2.4.b).
c. Insert the relative bar code (with the external barcode reader or using the virtual Windows CE keyboard pressing the grey button “Classifier ID”)

fig. 4.2.4.b

4.2.5 Conclusion of the analytical cycle

An analytical cycle regarding a single sample is finished when:

1. the sample is present and identifiable, by the corresponding alphanumeric co-ordinates, in the sample holder rack that holds it,
2. the relative result is present on the result printout regarding the sample holder rack that holds it.

Every time a sample holder rack is complete, the instrument will complete a printout of the results regarding the test tubes of the samples therein; also indicated on the printout is the code of the sample holder rack, the date, the time and the temperature of the analytical cycle, the installed software version and the serial number of the instrument (paragraph 3.4).

4.2.6 Conclusion of the daily analytic activity

At the end of the daily analytical activity and every time one desires to access the archive it is necessary to press the ‘Stop’ button. This operation allows the ‘Archive’ button to become active (“illuminated”) and at the same time to save all data obtained until that moment.

Before turning off the instrument’s main switch, ALWAYS press “STOP” (otherwise the data saving in the archive will be jeopardised).

5 CHAPTER 5

5.1 GENERAL RECOMMENDATIONS

The Ves-Matic Cube 80 is designed and constructed to require only a minimum amount of maintenance

For any intervention:
- disconnect the power from the instrument.
- use the personal protection features, foreseen during functioning
- do not remove barriers and do not avoid the security devices

In the case of leakage of biological material inside the instrument or contamination of its external surfaces use the features provided for decontamination and carry out the actions stated in the appropriate instructions described in paragraph 5.2

5.2 CLEANING/DISINFECTION OF THE INSTRUMENT

Attention: to carry out this procedure use the devices foreseen in the legislation in force for handling a biological hazard

Cleaning and decontamination of the external surfaces of the instrument:

1. All described operations must be conducted with the instrument switched-off.
2. Prepare a 1% solution of Virkon (registered trade mark) in a container: 10 g of powder in 1 litre of water. Dissolve the powder by shaking the container until the solution is homogeneous. For complete and detailed information on the properties of Virkon® visit the internet site: www.virkon.it
3. Use a wet cloth with the Virkon® solution on the external surfaces of the instrument that should be cleaned and decontaminated, taking care to comply with the regulations in force on the matter of biological hazard. Use the decontamination solution on the entire surface and clean while avoiding any contact with the internal parts of the instrument containing the electronic cards.
4. Leave to dry. Repeat the operations described in points 2 and 3 to conclude the cleaning and decontamination of the external surfaces of the instrument.

Cleaning and decontamination of the internal parts of the instrument

All operations must be conducted only by personnel authorised by Diesse Diagnostica Senese S.p.A. and must be done with the instrument turned off and with all parts exposed.

1. Prepare a 1% solution of Virkon®: dissolve 10 g of powder in 1 litre of water in a container, shaking carefully to obtain a homogenous solution. For complete and detailed information of the properties of Virkon® visit the internet site: www.virkon.it

2. Use a wet cloth with the Virkon® solution on the internal surfaces of the instrument that should be cleaned and decontaminated, taking care to comply with the regulations in force on the matter of biological hazard. Use the decontamination solution on the entire surface and carry out the cleaning operation between the electronic cards, avoiding any contact therewith
3. The internal electronic cards that are contaminated by the biological samples must be substituted with newly installed equivalent cards. The contaminated cards must be gathered in a plastic bag which is to be sealed and sent for disposal according to the regulations in force.

5.3 REPLACEMENT OF PRINTER PAPER

Procedure:

- Switch-off the instrument and disconnect from the power source.
- Lift the printer window.
- Remove the paper pin.
- Substitute the old paper roll with a new one.
- Lift the printer head, raising the appropriate lateral lever (indicated with A by the arrow in figs. 5.3.a and b). Insert the end of the paper strip in the opening of the paper guide, taking care to level it precisely with a pair of scissors and respecting the paper rotation direction

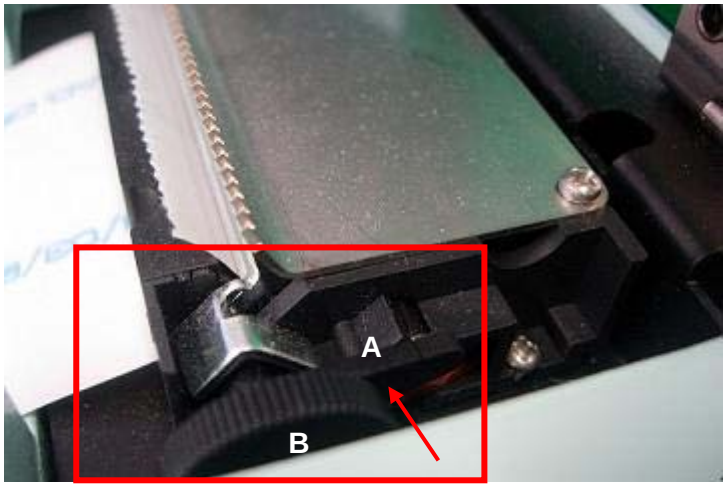


Fig.5.3 a

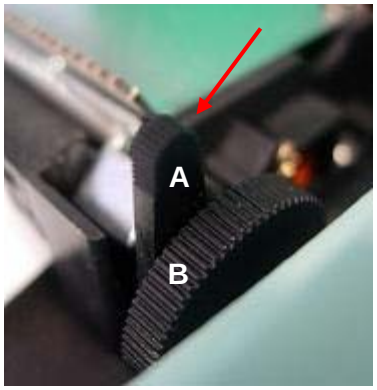


fig.5.3 b

- Connect the instrument to the power source and switch-on
- Push the paper until self-loading begins (fig. 5.3.c). It is possible to use a toothed roll as indicated by “B” (figs. 5.3.a, b) to facilitate loading.

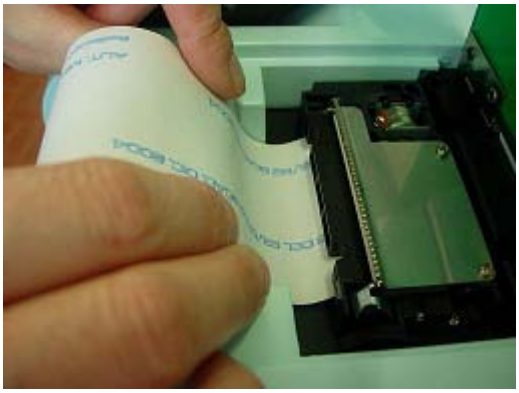


fig. 5.3. c

- Lower the print head lever.
- Let the paper move forward until extending from the front (figs.5.3 d, e).

fig.5.3 d

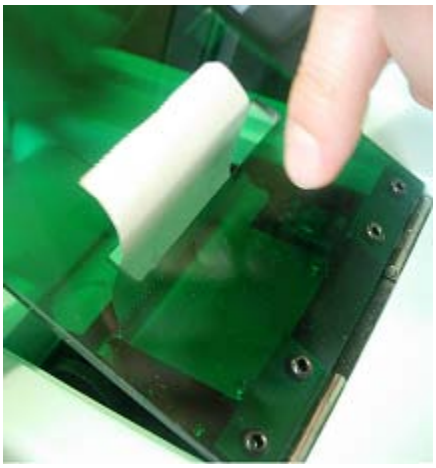


fig.5.3 e

fig.5.3 f

- Pull the paper through, close the window and extract the paper that extends from the front (fig.5.3 f).

5.4 REPLACEMENT OF THE FUSES

When it is necessary to substitute the fuses, the procedure to follow is the one described here after. Make the lid of the lodging of the fuses accessible (“Filtered socket with fuse holder lodging” fig. 5.4.a) which is located on the back of the instrument beneath the general power supply cable (fig. 5.4.a)

e power supply cable

Filtered socket with fuse holder lodging

fig. 5.4.a

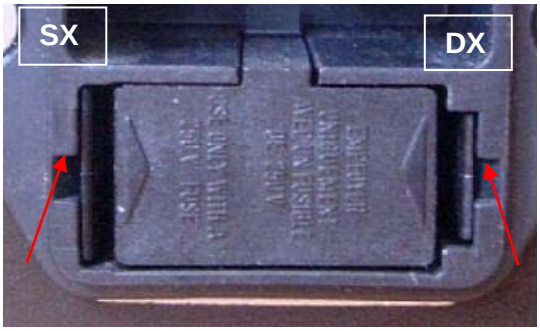


fig. 5.4.b

Insert a screwdriver with a flat head in the point shown in fig. 5.4.b, then push the right tab to the left, as indicated by the white arrow in fig. 5.4.c, repeat the operation with the left tab that, in this case, is pushed to the right as indicated by the red arrow in fig. 5.4.c.

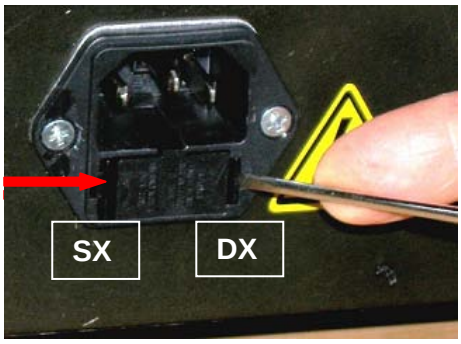


fig. 5.4. c

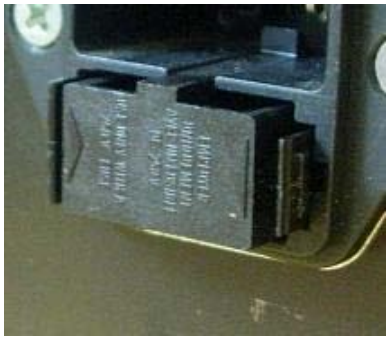


fig. 5.4.d

Pressing the tabs between thumb and forefinger it is possible to extract the fuse holder lodging completely from the filtered socket (fig. 5.4.d) and to proceed with the replacement of fuse(s) as shown in fig. 5.4.e.

fig. 5.4.e

fig. 5.4.f

fig. 5.4.g

Insert the fuse holder into its lodging (fig 5.4.f) pressing down in the way indicated by the arrow in fig. 5.4.g, until the tabs return with a click into their original position.

6 CHAPTER 6

6.1 TROUBLESHOOTING

The PC Tablet, besides performing command operations and control of the peripherals, constantly checks the most important parts of the instrument
When an anomaly is encountered the process in progress is automatically interrupted and a sound signal is sent; at the same time the type of breakdown or problem encountered is displayed on the screen.
The possible messages are the following:

MESSAGE AND FAULT	CAUSE AND SOLUTION
Device Error 0x01 (Positioner)	Besides possible electric defects, there can be mechanical obstructions that should be removed (see paragraph about independent management of some problems) If the problems persist, contact technical service.
Error of the chain movement.	
Device Error 0x04 (Mixing device)	Besides possible electric defects, there can be mechanical obstructions that should be removed (see paragraph about independent management of some problems) If the problems persist, contact technical service.
Error in mixer device of the test tube in the analysis module.	
Device Error 0x05 and 0x06 (Reader 1 or 2)	Besides possible electric defects, there can be mechanical obstructions that should be removed (see paragraph about independent management of some problems) If the problems persist, contact technical service.
Errors in the reader devices of the optical sensors.	
Device Error 0x08 (Sample holder)	Press the STOP button to interrupt the analysis cycle and let the rack exit by selecting “Unload sample holder rack” If the problems persist, contact technical service.
Error in the movement of the sample holder rack	
Device Error 0x10 (horizontal Pincers)	Besides possible electric defects, there can be mechanical obstructions that should be removed (see paragraph about independent management of some problems) If the problems persist, contact technical service.
Movement error along horizontal axis on pincers unit	
Device Error 0x11 (vertical pincers)	Besides possible electric defects, there can be

Movement error along vertical axis on pincers unit	mechanical obstructions that should be removed (see paragraph about independent management of some problems) If the problems persist, contact technical service.
Device Error 0x13 (Racks Detection) Error in pincer inside pincer unit.	Besides possible electric breakdowns, mechanical obstructions can be occur that must be removed (see paragraph 6.2) If the problem persists, contact technical service
Device Error 0x20 (Transponder) Error of the refill device of the Check Device	Contact technical service
Error test tube absent (Ph Chain) The system does not detect an expected test tube in the chain.	Besides possible electric breakdowns, mechanical obstructions can be verified that must be removed (see paragraph 6.2) If the problems persist, contact technical service.
Check Device running out The test counter is running out, the instrument has no more then 500 tests available (box is YELLOW)	Insert a new check device/Transponder in the instrument. If the problem persists after the refill, contact technical service.
Check Device empty The test count has run out (box is RED)	Insert a new check device/Transponder in the instrument. If the problem persists after the refill, contact technical service.
Error in refilling Check Device Problems in refilling the test counter	Insert a new check device/Transponder in the instrument. If the problem persists after the refill, contact technical service.
Verify front left micro switch Error in left micro switches on the front panel.	Verify the correct positioning of the front container on the indicated side of the micro switch. If the problem persists, contact technical service.
Verify front right micro switch Errors in right micro switch on the front panel.	Verify the correct positioning of the front container on the indicated side of the micro switch. If the problem persists, contact technical service.
Timeout Host Error of connection line to host computer.	Verify the correct connection of the cable on the rear of the Ves-Matic Cube 80. Verify the correct functioning of the IT network of the laboratory.
Printer: out of paper Printer paper ran out.	Insert a new roll of paper in the printer (see paragraph 5.3) If the problem persists, contact technical service.
Printer head is raised	Lift the lid of the printer and lower the head, using the

The printer head is raised .	black lever on the right side of the head. If the problem persists, contact technical service.
Printer: communication error	Verify that there is paper and the head position. If the problem persists, contact technical service.
Communication error between printer and PC Tablet.	

After any **ERROR** signal it is advisable to repeat the whole operation at least once, to ensure that the error isn't caused by external factors, like the momentary interruption or variation of electricity.

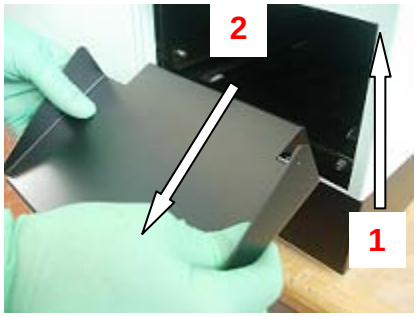
Switch the instrument off and wait a few seconds, turn the instrument on again and restart the cycle in the prescribed mode (at the start of the analysis procedure the instrument executes a reset of all internal systems.)

6.2 INDEPENDENT MANAGEMENT OF SOME PROBLEMS

ATTENTION: <u>The described procedures must be carried out only while the instrument is switched off. Before reactivating the instrument it is necessary to restore all safety covers</u>

6.2.1 Procedure for access to the Classifier module

1. Remove the two Insertion Extension Racks by sliding them upwards by about 1 cm and moving them to the outside to free them from the holding buttons (fig. 6.2.1.a)



Push the Insertion Extension Racks upwards, then move them outwards, following the order of the arrows (fig. 6.2.1 a)

fig. 6.2.1 a

2. Open the preparer module door and lift the front cover vertically about 1 cm, pushing from the bottom, so that it slides upwards.

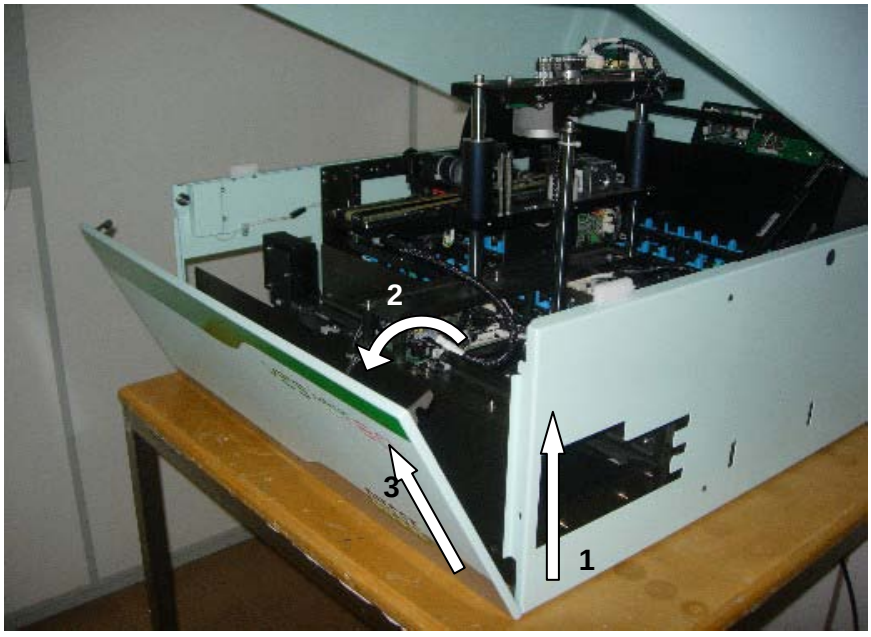


fig. 6.2.1.b.

3. Completely remove the front cover.

Verify whether or not there are any test tubes causing a block and remove them.

4. For reassembly follow the reverse procedure to the one described until the upper part of the cover is aligned with the lateral panels.

6.2.2 List of some error messages and their solution

When the instrument is in the “View Analysis Module” or “View Preparer module” mode it can indicate error messages on the screen in the “information bar” (see fig. 3.2.b). Some error messages and the operating instructions for their solution by the operator are shown below.

Verify front left micro switch: in this case it is advisable to verify the correct application of the front cover, without necessarily switching off the instrument.

Device Error 0x04 (Mixing device): the normal movement of the mixer is blocked, it is advisable to access the analysis module following, the procedure described in 6.2.1 and 6.2.2, with the instrument turned off, verify whether there are any mechanical blocks, then remove the sample near the mixer, switch the instrument on, press “Start” and verify that the “reset” (indicated in the information bar) occurs correctly.

Error Test Tube absent (Ph. Chain): this error may occur if the sample remains blocked in the rack caused by adherence generated by the incorrect labelling of the test tube (see paragraph 4.2.2) In this case, it is sufficient to restart the analysis to move on to the next sample.

7 CHAPTER 7

7.1 *EXTERNAL BARCODE READER*

The recording of the identification number of the sample holder rack can only occur by means of the external BAR CODE READER supplied with the instrument

GENERAL SPECIFICATIONS FOR CONNECTION:

Before connecting the external Barcode Reader verify that:

a. this is fitted with a cable with a female DB9 connector in DTE configuration with a current of 5Vdc on 9 pins (refer to the barcode reader instruction manual),
b. the signals on the DB9 female connector are compatible with the connector placed on the back of the instrument to which it is connected:

DB9 Male External barcode	
PIN	SIGNAL
2	Tx data to reader (not used)
3	Rx data from reader
5	GND
9	+ 5 V

TECHNICAL INFORMATION

- The electric levels of the signals are RS232 standard type
- The communication is one-way from the barcode reader to the machine.
- The transmission speed is 9600bit/s, the data format is 8 bit of data, 1 stop bit and no parity bit.
- The communication protocol is the ASCII type; the read barcode must be finished by the Carriage return (0x0d) character.

The reader must be connected, WHILE THE INSTRUMENT IS TURNED OFF, to the appropriate DB9 male placed on the back of the Window Group.

On turning on the instrument, if it is connected correctly, the reader will emit an acoustic signal. A similar signal is sent every time the reader obtains a barcode.

7.2 *CONNECTION TO THE HOST COMPUTER:*

Serial Protocol for communication with the Host Computer

7.2.1 Preface: Technical information

- The electric levels of the signals are the RS232C standard type.
- The transmission speed is 9600bit/s, the data format is 8 bit of data, 1 stop bit and no parity bit.
- The DB9 Male "RS232C" connector on the back panel of the Ves-Matic Cube 80 reflects the following pin-out:

PIN	SIGNAL
2	Rx data from Host
3	Tx data to Host
5	GND

7.2.2 Preface: Hexadecimal ASCII (HEX-ASCII) representation

In the protocol described below many of the parameters and data are represented in Hexadecimal ASCII (HEX-ASCII) format, in other words:
a byte with a value of 0x7A is represented by two ASCII characters: '7' (0x37) and 'A' (0x41), the first represents the most significant nibble and the second, the least significant.

Examples:

Original Byte	**HEX-ASCII Representation**	
Hexadecimal value	H character	L character
0x45	'4' (0x34)	'5' (0x35)
0xC8	'C' (0x43)	'8' (0x38)
0x6F	'6' (0x36)	'F' (0x46)
0x10	'1' (0x31)	'0' (0x30)

As can be noted this type of representation means that two ASCII characters are necessary for the representation of the value of one byte.

7.2.3 General remarks: Delay in replying

To allow the machine time to activate the reception mode it is necessary to enter a delay of 1 second on the reply and send the ACK frame and any reply together in a single frame.

7.2.4 Message Requesting Test Tubes to be Processed: Control 0x50

This message is sent from the Ves-Matic Cube 80 to the host computer. The message contains the test tube barcode. The host computer must reply to this message with a similar message containing the barcode, among the ones received from the Ves-matic Cube 80, for the samples that require ESR testing. (i.e. codes that have already been accepted by the host) and in the case of codes that have not yet been accepted by the host (thus unknown)
The management of the samples to executed because they have been accepted on the host and that of the samples to be executed although 'unknown' to the host, is based on an attribute (the terminator of the bar code) contained in the host's reply message (see 7.2.5)

Example 1 (WITHOUT management of 'unknown' codes)
The Ves-Matic Cube 80 sends 10 bar codes to the host, the host returns only 4 of the 10 received codes, that is only those that must be analyzed by the Ves-Matic Cube 80 (the other 6 samples will not be processed by the instrument), **this type of management is strongly not recommended**.

Example 2 (WITH management of 'unknown' codes)
The Ves-Matic Cube 80 sends 10 barcodes to the host, the host returns 4 codes with the attribute ESR to execute + 2 codes with the attribute "unknown code". The instrument will execute the 6 samples, at the end of the analysis it will send the results of the 4 codes with ESR to execute, while the other 2 'unknown' codes will stay in the pending database.

7.2.4.1 Request: Ves-Matic Cube 80 sends the following frame:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x30)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

7.2.4.1.1 H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value 'F' (0x46) / 'F' (0x46). This is the effective number of bytes contained in the **Data** field**.** In fact, the maximum number of bytes accepted in the DATA field is 255.

7.2.4.1.2 Data-1 .. *Data-n*: Data field. The data field for the message code 0x50 is composed as follows:

H-NUM / L-NUM (2 bytes HEX-ASCII)	**BarCode-1** (ASCII string max 15 characters)	**Terminator** of the Barcode-1 string (0x10)	**BarCode-2** (ASCII string max 15 characters)	**Term.** of the Barcode-2 string (0x10)	…..	**BarCode-n** (ASCII string max 15 characters)	**Term.** of the Barcode-n string (0x10)

H-NUM / L-NUM: Number of bar codes contained in the message, represented in HEX-ASCII

BARCODE-n: ASCII string with variable length, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 80 Barcode Reader.

Terminator: Each string of the barcode is terminated with the byte 0x10. This is because the length of this string is variable.
The number of bar codes contained in the data field is limited by the fact that the data field itself can contain a maximum of 255 bytes, in any case the bar codes are never truncated, but always complete with terminator.

7.2.4.1.3 H-CHK / L-CHK:
CheckSum of the message, represented in HEX-ASCII. The Checksum is calculated by carrying out the OR-exclusive of all the bytes sent from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

ATTENTION: for debugging purposes it is possible to disable the checksum control, replacing the H-COM bytes with the value of 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

7.2.4.2 Reply from the Host Computer
Upon receiving the message, the Host computer must first send an ACK message to acknowledge correct receipt and interpretation of the message; meaning that all the fields have the correct values and the checksum is correct, or a NACK message to indicate that the message contains one or more errors: inexact checksum, incorrect length of the data field, etc

7.2.4.2.1 ACK Message

ACK	H-ADD	L-ADD	ETX
(0x06)	(0x30)	(0x31)	(0x0D)

Timeout on ACK Message: 2 Sec.

7.2.4.2.2 NACK Message

NACK	H-ADD	L-ADD	**H-ERR**	**L-ERR**	ETX
(0x15)	(0x30)	(0x31)			(0x0D)

where: **H-ERR / L-ERR** are the HEX-ASCII representation of the error code defined according to the following table:

Error code	**Value of: H-ERR**	**L-ERR Value**	**Meaning**

0x00	**0x30**	**0x30**	**General Error**
0x04	**0x30**	**0x34**	**Checksum Error**
0x05	**0x30**	**0x35**	**Field value Error** **H-LEN / L-LEN**
0x06	**0x30**	**0x36**	**Data field Length Error**

Timeout on NACK Message: 2 Sec.

7.2.5 Reply Message with 0x50 Control Data

After having sent the ACK message, the host computer must send the real reply to the 0x50 message. This response will be identical to the message sent by the Ves-Matic Cube 80, with the only difference being that the barcodes sent will only be the ones that must be processed by the Ves-matic Cube 80 and with the other difference of the terminator 0x11 for the "unknown codes" (i.e. not yet accepted on the host computer and therefore also to be processed). Therefore the **H-LEN/L-LEN and H-NUM/L-NUM** fields may be different.

If none of the barcodes must be processed, the **Data** field will only contain the H-NUM / L-NUM (0x30 / 0x30 value) field and H-LEN /L-LEN will be equal to 0x30 / 0x32.

The data field for the 0x52 message code: consists of the following:

H-NUM / L-NUM (2 bytes **HEX-ASCII)**	**BarCode-1** (ASCII string max 15 characters)	**Terminator** of the Barcode string (0x10/0x11)	**BarCode-2** (ASCII string max 15 characters)	**Terminator** of the Barcode-2 string (0x10/0x11)	… ..	**BarCode-n** (ASCII string max 15 characters)	**Terminator** of the Barcode-n string (0x10/0x11)

H-NUM / L-NUM: Number of bar codes contained in the message, represented by HEX-ASCII

BARCODE-n: ASCII string with variable length, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 80 Barcode Reader.

Terminator: Every string of the bar code is terminated by a 0x10 byte or a 0x11 byte (for "unknown" codes). This allows the management of the variable length of the codes as well the management of "unknown codes".

The number of bar codes contained in the data field is limited by the fact that the data field itself can contain a maximum of 255 bytes, in any case the bar codes are never truncated, but always complete with terminator.

If the bar code string terminates with a 0x10 byte; this means that the sample must be processed by the Ves-Matic Cube 80, at the end of the examination the result will be printed and stored in the Historic Database.

If the bar code string terminates with a 0x11 byte, this means the code of the sample is unknown; in this case the Ves-Matic Cube 80 will process the sample but at the end of the examination the result will not be printed and it will be stored in the Pending Database.

Timeout on Message with Data: 5 Seconds.

7.2.5.1 Error on Reply Message with Data

If the Ves-Matic Cube 80 detects an error in the receipt of the message it will repeat the transaction from the beginning and resend the request message indicated in paragraph 7.2.4.1

7.2.6 Message for sending Results: 0x51 Control

This message is sent from the Ves-Matic Cube 80 to the host computer. The message contains the results of the analysis performed on one or more samples. The host computer must only reply to this message with an ACK or NACK type message to notify the successful receipt of the results or the presence of errors in the message.

N.B.: the samples that were analyzed by the instrument with the attribute “unknown code” are not sent automatically at the end of the analysis process but can only be sent manually by the operator by means of the command “Send to host” from the management menu of the pending database.

7.2.6.1 Control: Ves-Matic Cube 80 sends the following frame:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x31)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

7.2.6.1.a H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value ‘F’ (0x46) / ‘F’ (0x46). This is the effective number of bytes contained in the data field**.** In fact, the maximum number of bytes accepted in the Data field is 255.

7.2.6.1.b Data-1 .. Data-n: Data field. The data field for the message code 0x51 is as follows:

H-PRO / L-PRO (2 bytes HEX-ASCII)	**Test Tube-1 Record**	……	**Test Tube-n Record**

H-PRO / L-PRO: Number of Test Tube records contained in the message, represented in HEX-ASCII.

The Test Tube Record number contained in the data field is limited by the fact that the data field itself is able to contain up to a maximum of 255 bytes, in any case the test tube records are never truncated.

7.2.6.1.b.1 Test Tube record:

Barcode (ASCII string max 15 characters)	**Terminator** of the Barcode string (0x10)	**DATA ANALYSIS** ASCII String 6 characters	**ANALYSIS TIME** ASCII String 4 characters	**ESR** ASCII String 4 characters	**H-FLAGS**	**L-FLAGS**	**RACK ID** String ASCII 4 characters	**POSITION** String ASCII String 2 characters

BARCODE: ASCII string with variable length, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 80 Barcode Reader.

Terminator: The barcodes string terminates with the 0x10 byte. This is because the length of this string is variable.

DATA ANALYSIS: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

ANALYSIS TIME : String of 4 characters without **"hhmm"** terminator, where:
"hh" = hour of the day, from "00" to "23" ASCII.
"mm" = Minutes, from "00" to "59" ASCII.

ESR: Value of the ESR measured, ASCII string without terminator: from " 0" (3 Spaces + '0') transmitted in the case of an error, to "140" (1 Space + "140"). If the result is higher than 140 the string will be ">140".

EXAMPLES: See following table:

ESR value	String sent	Bytes of the string
1	" 1"	0x20, 0x20, 0x20, 0x31
100	" 100"	0x20, 0x31, 0x30, 0x30
>140	">140"	0x3E, 0x31, 0x34, 0x30

N.B.: If sample holder rack traceability has been activated, the ESR result may be 0 (without error flag), in this case it means that the sample in question has not been analysed, as requested by the host.

H-FLAGS / L-FLAGS: Bitmap with 8-bit of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	Sample High	Sample tube overfilled
1	Sample Low	Sample tube underfilled (<1.5 ml)
2	Sample Absent	Test Tube Empty
3	Reading error	General reading error
4	QC PASS	Reserved for samples with control blood
5	QC FAIL	Reserved for samples with control blood
6-7	-	Reserved

EXAMPLES:

- In the case of a “Sample High” error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a “Sample Absent” error the Bit 2 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x04 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x34.

Management of UNCERTAIN RESULT

If a Test Tube record is sent with an ESR value equal to 0 and with an error flag active (Bit 3 set to 1), the result (ESR=0) must be interpreted by the Host as ‘Sample reading error’ (for non-analysed samples the error flag is not active further to a host request).
If a Test Tube record is sent with an ESR value different from 0 and with an error flag active (Bit 3 set to 1), the result (ESR different from 0) must be interpreted by the Host as an ‘Uncertain Result’, in the report the result is printed and indicated with an asterisk.

RACK ID: A string of 4 characters without terminator identifies the sample holder rack in which the sample has been repositioned.

POSITION: A string of 2 characters without terminator identifies the coordinates of the position in which the sample has been repositioned in the sample holder rack.

7.2.6.1.c. H-CHK / L-CHK: CheckSum of the message, represented in HEX-ASCII. The Checksum is calculated by carrying out the OR-exclusive of all the bytes sent from STX to ETX inclusive. The resulting hexadecimal value is then converted into HEX-ASCII and the two characters that represent it are sent.

ATTENTION: for debugging purposes it is possible to disable the checksum control, replacing the H-COM bytes with the value of 0x44 instead of 0x35. In this case the two bytes of the checksum are still sent but their value will be insignificant. The Host computer must also manage any possible cases in which the checksum is disabled.

7.2.6.2 Reply from the Host Computer

Upon receiving a message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message, meaning that all the fields have the correct values and the checksum is correct; or a NACK message to indicate that the message contains one of more errors: inexact checksum, incorrect length of the DATA field, etc.

7.2.7 Message for sending QC (Quality Control) Sample Data: Control 0x52

This message is sent from the Ves-Matic Cube 80 to the host computer. The message contains the results of the analysis performed on one or more samples. The host computer must only reply to this message with an ACK or NACK type message to notify the successful receipt of the results or the presence of errors in the message.

7.2.7.1 Control: Ves-Matic Cube 80 sends the following frame:

STX (0x3E)	H-BLK (0x30)	L-BLK (0x30)	**H-LEN**	**L-LEN**	H-ADD (0x30)	L-ADD (0x31)	H-COM (0x35)	L-COM (0x32)	**Data-1**	**...**	**Data-n**	ETX (0x0D)	**H-CHK**	**L-CHK**

The hexadecimal values indicated in brackets are constant values for this message. The fields in bold print are variable and are described below:

7.2.7.1.a H-LEN / L-LEN: Length of the data field, from Data-1 to Data-n inclusive, represented in HEX-ASCII. Maximum Value ‘F’ (0x46) / ‘F’ (0x46). This is the effective number of bytes contained in the data field**.** In fact, the maximum number of bytes accepted in the DATA field is 255.

7.2.7.1.b Data-1 .. Data-n: Data Field. The data field for the message code 0x52 is composed as follows:

QC Data	**QC Test Tube Record:**

7.2.7.1.b.1 QC Data

Batch No. (ASCII string 6 characters)	**EXPIRY DATE** ASCII String 6 characters	**H-VALMIN**	**L-VALMIN**	**H-VALMAX**	**L-VALMAX**

BATCH No.: ASCII string of 6 characters. Identifies the production batch of the control blood.

EXPIRY DATE: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

H-VALMIN / L-VALMIN: The minimum value of the acceptable range for the control blood, represented in HEX-ASCII.

H-VALMAX / L-VALMAX: The maximum value of the acceptable range for the control blood, represented in HEX-ASCII.

7.2.7.1.b.2. QC Test Tube Record:

Barcode (ASCII String max 15 characters)	**Terminator** of the string Barcode (0x10)	**ANALYSIS DATE** ASCII String 6 characters	**ANALYSIS TIME** ASCII String 4 characters	**ESR** ASCII String 4 characters	**H-FLAGS**	**L-FLAGS**	**RACK ID** ASCII String 4 characters	**POSITION** ASCII String 2 characters

BARCODE: ASCII string with variable length, maximum of 15 characters allowed. This is the barcode as it is read by the Ves-Matic Cube 80 Barcode Reader.

Terminator: The barcodes string terminates with the 0x10 byte. This is because the length of this string is variable.

DATA ANALYSIS: String of 6 characters without **"DDMMYY"** terminator, where:
"DD" = day of the month, from "01" to "31" ASCII.
"MM" = Month of the year, from "01" to "12" ASCII.
"YY" = Year of the century, from "00" to "99" ASCII.

ANALYSIS TIME : String of 4 characters without **"hhmm"** terminator, where:
"hh" = hour of the day, from "00" to "23" ASCII.
"mm" = Minutes, from "00" to "59" ASCII.

ESR: Value of the ESR measured on the QC sample, ASCII string without terminator: from " 0" (3 Spaces + '0') transmitted in the case of an error, to "140" (1 Space + "140"). If the result is higher than 140 the string will be ">140".

EXAMPLES: See following table:

ESR value	String sent	Bytes of the string
1	" 1"	0x20, 0x20, 0x20, 0x31
100	" 100"	0x20, 0x31, 0x30, 0x30
>140	">140"	0x3E, 0x31, 0x34, 0x30

H-FLAGS / L-FLAGS: 8-bit Bitmap of the sample errors, represented in HEX-ASCII. The following table illustrates the errors:

Bit	Error	Description
0	**Sample High**	**Blood column too high**
1	**Sample Low**	**Blood column too low**
2	**Sample Absent**	**Test Tube Empty**
3	**Abnormal**	**Error in acquisition of height**
4	**QC PASS**	**The ESR of the QC measured is within the acceptability range**
5	**QC FAIL**	**The ESR of the QC measured is outside the acceptability range**
6-7	**-**	**Reserved**

EXAMPLES:

- In the case of a “Sample High” error the Bit 0 (least significant) will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x01 hexadecimal value and its HEX-ASCII representation will be 0x30 / 0x31.
- In the case of a “QC Fail” error the Bit 5 will be set to one and all the others to zero, therefore the byte of the Flags will have a 0x20 hexadecimal value and its HEX-ASCII representation will be 0x32 / 0x30.

RACK ID: A string of 4 characters without terminator identifies the sample holder rack in which the sample has been repositioned.

POSITION: A string of 2 characters without terminator identifies the co-ordinates of the position in which the sample has been repositioned in the sample holder rack.

7.2.7.2 Reply from the Host Computer

Upon receiving a message, the Host computer must send an ACK message to acknowledge correct receipt and interpretation of the message, meaning that all the fields have the correct values and the checksum is correct; or a NACK message to indicate that the message contains one of more errors: inexact checksum, incorrect length of the data field, etc.

7.2.8 Example of Serial Protocol

1. Example for the ESR analysis request on two samples (two barcodes, see paragraph 7.4.1)

ATTENTION: The non-printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..]

Ves-Matic Cube 80 TX:

>00140150020109105 3[0x10]20586743[0x10][0x0D]36

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM:	SAMPLE 1 BAR CODE + TERMINATOR	SAMPLE 2 BAR CODE + TERMINATOR	ETX	H/L CHK:
>	00	14	01	50	02	01091053[0x10]	20586743[0x10]	[0x0D]	36

STX : [0x3E] '>'.
H/L BLK : fixed value '00'
H/L LEN: number of characters in the data field (14 hex = 20 characters: 2 for H/L NUM + 9 SAMPLE 1 BARCODE + TERMINATOR + 9 SAMPLE CODE 2 BARCODE + TERMINATOR)
H/L ADD : fixed value '01'
H/L COM : command code "for sample code to process request": '50'.
H/L NUM: number of barcode included in this message (02 hex = 2 bar codes)
SAMPLE 1 BAR CODE + TERMINATOR
SAMPLE 2 BAR CODE + TERMINATOR
ETX : character [0x0D]
H/L CHK: "xor" of all characters from STX to ETX included.

2. Example of the authorisation request to Host for two bar codes of two samples and the authorisation reply for the analysis of only the second (see paragraph 7.2.4)

ATTENTION: The non-printable characters (<0x20) are represented with their hexadecimal value between brackets [0x..]

Ves-Matic Cube 80 TX Request:

>00140150020109105 3[0x10]20586743[0x10][0x0D]36

Host Message TX ack:

[0x06]01[0x0D]

Host Reply TX:

>000B01500120586743[0x10][0x0D]5D

STX	H/L BLK	H/L LEN	H/L ADD	H/L COM	H/L NUM:	SAMPLE 2 BAR CODE + TERMINATOR	ETX	H/L CHK:
>	00	0B	01	50	01	20586743[0x10]	[0x0D]	5D

STX : [0x3E] '>'.
H/L BLK : fixed value '00'
H/L LEN: number of characters present in the data field (0B hex = 11 characters: 2 for H/L NUM + 9 SAMPLE 2 BAR CODE + TERMINATOR
H/L ADD :fixed value '01'
H/L COM : command code "for sample code to be processed request": '50'.
H/L NUM: number of barcodes included in this message (01 hex = 1 bar code)
SAMPLE 2 BAR CODE + TERMINATOR
ETX : character [0x0D]
H/L CHK: "xor" of all characters from STX to ETX included.

BIBLIOGRAPHY

1. Westergren A.: The Technique of the red cell sedimentation reaction. Am. Rev. Tuberc. 1926; 14: 94-101.
2. Silvestri M.G., Cozza E., Bertoli G., Federzoni C., Marzullo F.: Determinazione Automatica della velocità di Eritrosedimentazione. Assoc. Italiana Patologi Clinici XXXIV Congresso Nazionale 1984, Abstract.
3. De Franchis G., Carraro P., D'Osualdo A., Di Vito S.N., Paleari C.D.: Valutazione del Sistema Ves-Tec/VES-MATIC. Confronto con il Metodo ICSH. Il Patologo Clinico 1985; 4:120.
4. Jou J.M., Insa M.J., Aymeric M., Vives Corrons J.L.: Evaluación de un Sistema Totalmente Automático para realizar la Velocidad de Sedimentación Globular. Sangre 1988; 33 (6):474-478.
5. Prischl F.C., Schwarzmeier J.D.: Automatisierte Bestimmung der Blutkor-perchensenkungsgeschwindigkeit (VES-MATIC): Einsatz im Krankenhaus. Berichte der OGKC 1988; 11:112-114.
6. Vatlet M., Brasseur M., Poplier M. et al.: Evaluation of the DIESSE VES-MATIC for the Automated Determination of the Erythrocyte Sedimentation Rate (ESR). Belgian Hematological Society Meeting 1989, Abstract.
7. Vallespì Solè T.: Valor Actual de la Velocidad de Sedimentación Globular. Lab 2000 1989; 19:5-14.
8. Fernández de Castro M., Fernández Calle P., Viloria A., Larrocha C., Jimenez M.C.: Valoración de un Sistema Alternativo Totalmente Automático para la Determinación de la Velocidad de Sedimentación Globular. Sangre 1989; 34 (1):4-9.
9. Koepke J.A., Caracappa P., Johnson L.: The Evolution of the Erythrocyte Sedimentation Rate Methodology. Labmedica 1990; Feb-Mar : 22-24.
10. Caswell M., Stuart J.: Assessment of DIESSE VES-MATIC automated system for measuring erythrocyte sedimentation rate. J. Clin. Pathol. 1991; 44: 946-949.
11. Manley R.W.: J. Clin. Pathol. 1957; 10: 354.
12. ICSH: Recommendation for Measurement of Erythrocyte Sedimentation Rate of Human Blood. Amer. J. Clin. Pathol. 1977; 68 (4): 505-507.
13. ICSH: Guidelines on Selection of Laboratory Tests for Monitoring the Acute Phase Response. J. Clin. Pathol. 1988; 41: 1203-1212.
14. ICSH Recommendations for measurement of erythrocyte sedimentation rate. J. Clin. Pathol. 1993; **46**: 198-203
15. How to Define and Determine Reference Intervals in the Clinical Laboratory: Approved Guideline"EA-ASSE-2000-NCCLS

APPENDIX A: EC DECLARATION OF COMPLIANCE

EC DECLARATION OF COMPLIANCE

pursuant to the EEC 98/79 directive relating to in vitro medical-diagnostic devices - IVDD

Diesse Diagnostica Senese S.p.A.

The company DIESSE DIAGNOSTICA SENESE S.p.A. with its registered office in Milan, Via San Vittore 36/1

hereby declares

that the design, type of manufacture of the in vitro Diagnostic Device CE-IVDD described below and the version distributed on the market,

complies with

EEC DIRECTIVE 98/79 RELATING TO IN VITRO MEDICAL DIAGNOSTIC DEVICES ("IVDD")

through the completion of Appendix III (except section 6) and the essential requirements set out in Appendix I.

This declaration shall be invalid if:
- unauthorised modifications are made to the unit
- the instrument is used improperly
- technical interventions are made on the instrument by unauthorised staff
- non-original spare parts are used.

Product: **Automatic system for the examination of ESR Speed**

Type: **Ves-Matic Cube 80**

Technical data: **90-264 Vac (50-60 Hz) Pwr; 265VA**

complies

in whole and in all of its parts to the following standards and related amendments:

EN 61010-1 "Safety directives for electrical equipment for measurement, control and laboratory use– Part 1: General directives".

EN 61326-1 "Electrical equipment for measurement, control, laboratory use – EMC directives – Part 1: General directives".

therefore meets the minimum requirements of the following EEC directives and related amendments:

Low voltage EEC Directive (2006/95 EEC)

Electromagnetic compatibility EEC Directive (89/336/EEC) and (93/68/EEC)

Monteriggioni,

01/09/2005

Signature: R&D Director

Appendix B: WARRANTY CERTIFICATE

Ves-Matic Cube 80 Warranty Certificate

S/N Certificate

DIESSE DIAGNOSTICA SENESE S.p.A. subjects all its products to strict quality controls. However, should the instrument show signs of malfunctioning despite these controls, you are invited to contact the authorised Technical Assistance Centre indicated to you at the time of delivery of the instrument.

Limits of liability

DIESSE DIAGNOSTICA SENESE S.p.a. assumes all liability for damages arising from manufacturing defects or malfunctioning of the instrument during the **foreseen use** of the same. It declines any other type of liability.

General warranty regulations:

DIESSE DIAGNOSTICA SENESE S.p.A. guarantees the Ves-Matic Cube 80 for a period of 12 months from the delivery date (the date on the transport document shall be valid) for defects in the materials or manufacturing.

Should the product prove to be defective during the guarantee period the authorised Assistance Centres will repair it and you will only be charged for transport costs.

General Conditions:

The warranty shall only be acknowledged if the warranty certificate is sent within 30 days of the delivery date, attaching a copy of the transport documents thereto.

The materials and manufacture of this product shall not be considered as defective if the instrument has been adapted, modified or adjusted to comply with national or local standards in force in a country where they differ from those for which the product has originally been designed and constructed. This warranty shall not cover said adaptations, modifications or adjustments or any attempts at the same, irrespective of whether performed correctly or incorrectly, or any damage deriving from the same.

This warranty shall not cover:

eriodic checks, maintenance and repairs or replacement of parts due to normal wear and tear,

ansport costs and risks linked directly or indirectly to the warranty of this product, including the transfer from the assistance centre to the customer's address, damage deriving from erroneous use, negligence during use, erroneous installation, knocks and falls. Unsuitable voltage connections, use in environments with extreme conditions, damage caused by liquids being spilt inside, etc., or from any other accidental cause.

nalfunctioning of the instrument due to modifications or repairs carried out thereon by unauthorised third parties.

damage caused by the assembly of parts or components not approved by the manufacturer.

No interventions carried out under warranty shall interrupt or prolong the duration thereof for any reason whatsoever.

DIESSE DIAGNOSTICA SENESE S.p.A.

VIA DELLE ROSE 10 • 53035 MONTERIGGIONI • SIENA •ITALY

Tel. 0577 / 58.71.11
Fax 0577 / 31.86.90

Ves-Matic Cube 80 Warranty Certificate

S/N Certificate

Copy to be FILLED OUT and RETURNED to:

DIESSE DIAGNOSTICA SENESE S.p.A.

Via delle Rose 10 • 53035 Monteriggioni • Siena •Italy

S/N Certificate

INSTRUMENT _____ MODEL _____ SN# 200□-□□-□□□□

CUSTOMER/COMPANY _____

ADDRESS _____

CITY _____ ZIP CODE _____ STATE _____

D.D.T. no. _____ of _____

DEALER'S DATA

NAME/COMPANY _____

ADDRESS _____

INSTALLER'S DATA

NAME/COMPANY _____

ADDRESS _____

Remarks:

Appendix C: ASSISTANCE REQUEST FORM

Modulo Segnalazione/Reclamo DATA

Prodotto:	**Cliente:**
Matricola:	**Referente:**
Release SW:	Indirizzo:
D.D.T.	Tel:
Data	Fax:
Garanzia SI ☐ NO ☐	E-mail:

ULTIMO INTERVENTO TECNICO sul prodotto:
Eseguito da: _____ In Data: _____

DESCRIZIONE DETTAGLIATA DEL PROBLEMA

CONSIDERAZIONI VARIE DEL CLIENTE

USO INTERNO

Tipologia di reclamo:	☐	Fornitura	
	☐	Prodotto	
	☐	Servizio Tecnico	
Segnalazione	☐	Uff.Commerciale	_____
da inoltrare a:	☐	Uff.Tecnico	_____
	☐	Uff.Acquisti	_____
	☐	Ass.Qualità	_____
	☐	_____	_____
Tempi risposta	☐	entro _____ gg	
	☐	URGENTE	

Ritornare a _____ Fax: _____
E-mail: _____

Note:
Al fine di meglio comprendere e risolvere il guasto segnalato consigliamo di:
1.Compilare il presente modulo in tutte le sue parti
2. Allegare al presente modulo (se disponibile):
- la documentazione fornita dal cliente (es.report di stampa; fotografie;ecc…)
- la documentazione fornita dal personale di Service (es.stampa dei settings;reports;ecc…)

FIRMA _____ DATA _____

Pag. 1 di

DIESSE ASSISTANCE SERVICE	**CUSTOMER CARE** Via del Pozzo 5, 53035 Monteriggioni (SI), Italy Tel. ++39 0577 319556 Fax. ++39 0577 319020 e-mail: customercare@diesse.us

Appendix D: ACCESSORIES, SPARE PARTS AND CONSUMABLES

- 2 Sample holder racks [Ref: : R30003650]
- 2 Micro switch keys [Ref: : R10343131]
- 1 Roll of thermal paper h.mm l=57 D=50 [Ref: : R12300000]
- 2 5x20mm UL 5A delayed fuse blocks [Ref: : R20400070]
- 1 3x0.75 L =2m SCHUKO 90°-C1 Power cable3 [Ref: : R21890040]
- 1 SVT PLUG USA/OUTLET VDE 2MT UL Power cable [Ref: R21890370]
- 1 Z-3080+Cable CAB50607-R9 Barcode reader [Ref: : R20550510]

Consumables

▪ Check device Transponder RF 1K for Ves-Matic Cube (1000 tests)	[Ref: 10292]
▪ Check device Transponder RF 5K for Ves-Matic Cube (5000 tests)	[Ref: 10291]
▪ Check device Transponder RF 10K for Ves-Matic Cube (10000 tests)	[Ref: 10290]
▪ ESR Control 9 ml (2 Normal Bottles + 2 Abnormal Bottles)	[Ref: 10430]
▪ ESR Control 9 ml (1 Normal Bottle + 1 Abnormal Bottle)	[Ref: 10434]
▪ Thermal paper for printer (4packets)	[Ref: 10403]

Appendix E: REQUEST FORM for ACCESSORIES, SPARE PARTS AND CONSUMABLES

Fill out and send a legible copy of the following to:

DIESSE ASSISTANCE SERVICE	**CUSTOMER CARE** Via del Pozzo 5, 53035 Monteriggioni (SI), Italy Tel. ++39 0577 319556 Fax. ++39 0577 319020 e-mail: customercare@diesse.us

Spare Parts Request Form

INSTRUMENT _____ MODEL _____ SN# 200□-□□-□□□□

CUSTOMER/COMPANY _____

ADDRESS _____

CITY' _____ ZIP CODE _____ STATE _____

T.D. n° _____ of _____

Remarks:

Code	Description	Pack.	Requested quantity

Date _____ . Signature _____.

Appendix F: METHOD MANUAL ACCORDING TO THE WESTERGREN TECHNIQUE

METHOD MANUAL ACCORDING TO WESTERGREN'S TECHNIQUE FOR DETERMINING THE ESR.

In order to measure the ESR according to Westergren's technique follow the recommendations of the International Committee for Standardisation in Haematology (ICSH) (bibliog. ref.12/13), outlined below.

Materials

Blood collected not more than three hours earlier with EDTA-K2 (1.5±0.25 mg per ml of blood) or with EDTA-K3 (1.7±0.3 mg per ml of blood). The haematocritical value must be between 30 and 36% (PCV - packed cell volume 0.33 ± 0.03).

- Anticoagulant/diluting solution consisting of trisodium citrate dehydrate 109 mmol/L (3.28 g dissolved in 100 ml of distilled water).

Glass sedimentation test tubes with the following dimensions: total length 300±1.5 mm, internal diameter 2.55±0.15 mm with a uniformity of ±0.05 mm, graded scale 200±0.35 mm long, subdivided into 10 mm steps or less with a maximum error tolerance between two consecutive divisions of 0.2 mm; the test tubes must be cleaned, dried and free of any residual traces of detergent before use.

Supporting rack for holding the test tubes in a perfectly vertical position (±1°) and structured so as to be completely stable to prevent any spillage of the blood from the test tubes.

Procedure

Dilute the blood collected in EDTA, after careful though not too vigorous shaking, with the citrate 109 mmol/L in a proportion of 4+1 (for example, 2 ml of blood + 0.5 ml of citrate); mix the blood with the citrate carefully for a long time, but not vigorously, and draw up into Westergren test tubes; place the test tubes in the supporting rack making sure not to expose to direct sunlight, vibrations or impact; after exactly 60 minutes read the distance in mm between the lower meniscus of the plasma and the level of the column of sedimented erythrocytes.

Appendix G: QUICK-START INSTRUCTIONS

Excerpt from this Operating Manual

These quick start instructions are directed only to expert users with a good level of knowledge of the entire contents of this manual.

- Turn the instrument on using the main switch, situated to the left of the power cable on the back of the instrument, turning it to position **"I"** (fig. 2.2.5).
- Press the START button, wait for the Reset to be completed.
- Check that the labels adhere perfectly to the test tubes: the adhesive parts, if detached, could cause friction during the mechanical movement systems (inserter, ejector, and sorter), creating inserting and ejecting problems in the analytical chain and possible blocks of the reading sensors.
- Blood sample level: The minimum acceptable level is ≥1.5 ml; maximum acceptable level is < 4 ml.
- No special preparation of the test tubes is required, since the Ves-Matic Cube 80 uses the ones coming from another analytical system (CBC examination); it is nevertheless advisable to comply with the ICSH standards.
- Insert the rack in its housing (see figure 4.2.3c). Remember that the rack loading positions are only the ones with a red interior (see figure 4.2.4a). The remaining positions are used by the machine to unload the analysed samples.
- Once the rack has been inserted, type the relative barcode.
- Press the STOP button to interrupt the analysis.
- ATTENTION! Do not switch off the instrument during the working phases or during the Reset procedure. To safeguard the database it is advisable that the machine is switched off ONLY after pushing the STOP button on the display, awaiting completion of the movements.
- At the end of the daily analytical activity and every time access to the archive is required it is necessary to press the 'Stop' button. This activates ('illuminates') the 'Archive' button and at the same time saves all data obtained until that moment.
- It is advisable to press the 'Stop' button ALWAYS before turning the main switch of the instrument off (see paragraph 3.2.1, description of the "Stop" button function).

DIESSE Diagnostica Senese SpA
Via del Pozzo, 5 - Loc. S. Martino • 53035 Monteriggioni (SI) Italy
Tel.: ++39/0577/31.95.60/61/50 • Fax: ++39/0577/31.87.63

http://www.diesse.it e-mail:salesoffice@diesse.it